UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRIS PHARMA, INC., Plaintiff, **v.** **TEVA PHARMACEUTICALS USA, INC.,** Defendant.	Civ. No. 20-05212 (KM)(ESK)

KEVIN MCNULTY, U.S.D.J.:

This is a Hatch-Waxman action for infringement of five patents: United States Patent No. 9,545,399 ("the '399 patent"), United States Patent No. 9,844,544 ("the '544 patent"), United States Patent No. 9,844,545 ("the '545 patent"), United States Patent No. 11,103,494 ("the '494 patent"), and United States Patent No. 11,103,495 ("the '495 patent") (collectively, the "asserted patents").

The action is brought by Tris Pharma Inc. ("Tris"), a pharmaceutical company that holds the asserted patents and sells an embodiment of the patents, a chewable extended-release medication for attention deficit hyperactivity disorder ("ADHD") called QuilliChew ER® ("QuilliChew"). The defendant is Teva Pharmaceuticals USA, Inc. Teva has filed Abbreviated New Drug Application No. 214202 ("ANDA"), seeking to produce and sell a generic version of QuilliChew. Tris alleges that Teva's proposed generic product would infringe claims 22 and 24 of the '399 patent; claim 37 of the '544 patent; claims 17, 23, 24, and 28 of the '545 patent; claim 28 of the '494 patent; and claim 23 of the '495 patent (collectively the "asserted claims"). Teva asserts that those patent claims are invalid for obviousness or indefiniteness. Assuming the claims are valid, Teva generally denies that its ANDA product would infringe,

except that it concedes infringement of claim 28 of the '494 patent and claim 23 of the '495 patent. (DE 165 ¶ 125–26.)[1]

The Court conducted a bench trial on these issues beginning on May 23, 2022 and concluding on May 26, 2022. The parties have submitted post-trial briefing. (DE 197, 199, 201, 204.) This Opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a). The findings of fact are based on the Court's observations and credibility determinations of the witnesses who testified at trial and a thorough review of all the evidence.

My validity conclusions are as follows:

1) Claim 24 of the '545 patent is fully invalid for obviousness;

2) the $AUC_{0-\infty}$ and C_{max} elements, insofar as they are incorporated in dependent claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent, are invalid;[2]

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[1] I will cite to the record as follows:

DE __	=	Docket Entry in this action
Def. Br.	=	Teva's Corrected Opening Post-Trial Brief (DE 199)
Def. Response	=	Teva's Corrected Post-Trial Response Brief (DE 204)
DTX	=	Defendants' trial exhibits
JTX	=	Parties' joint trial exhibits
PTX	=	Plaintiffs' trial exhibits
Pl. Br.	=	Tris's Opening Post-Trial Brief (DE 197)
Pl. Response	=	Tris's Post-Trial Response Brief (DE 201)
1T	=	May 23, 2022 Bench Trial Transcript (DE 182)
2T	=	May 24, 2022 Bench Trial Transcript (DE 186)
3T	=	May 25, 2022 Bench Trial Transcript (DE 188)
4T	=	May 26, 2022 Bench Trial Transcript (DE 183)

[2] As discussed in more detail below, these claims are all dependent claims. They are dependent, respectively, upon claim 1 of the '399 patent, claim 28 of the '544 patent, claim 1 of the '545 patent, and claim 26 of the '494 patent. It is those independent claims that include limitations related to $AUC_{0-\infty}$ and C_{max}. A dependent claim, however, may be found to be valid even if the independent claim is found to be

3) Claim 23 of the '495 patent, which does not include any limitations related to $AUC_{0-\infty}$ or C_{max}, is fully valid.

4) Teva's claims of indefiniteness are rejected.

On the infringement issue, I find that Teva's ANDA product infringes all of the asserted claims[3] except for claim 24 of the '545 patent, because it is invalid for obviousness.[4]

I. FINDINGS OF FACT

A. Procedural Background

On April 28, 2020, Tris filed a complaint for infringement of the asserted patents based on Teva's ANDA filing, which sought approval to market a generic version of QuilliChew (the "ANDA product"). (DE 1.) The complaint alleged direct infringement as well as induced and contributory infringement of the asserted patents. At trial, however, Tris's arguments focused solely on direct infringement.

Following discovery, a *Markman* hearing was held on July 13, 2021. (DE 100.) I issued a claim construction opinion on August 25, 2021. (DE 106.) On May 9, 2022, both parties filed motions in limine, which I have held in abeyance and will resolve as necessary in this Opinion.[5] (DE 153, 155.) On

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fully invalid. *See* 35 U.S.C. § 282(a); *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1377 (Fed. Cir. 2018). Thus, I must analyze whether the dependent claims are invalid on their own terms. Doing so, I find that only claim 24 of the '545 patent is fully invalid. The remaining asserted claims are valid and were infringed by Teva's ANDA product.

[3] As noted, Teva concedes infringement as to claim 28 of the '494 patent and claim 23 of the '495 patent.

[4] Although I have found invalid the $AUC_{0-\infty}$ and C_{max} elements of the claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, and 28 of the '545 patent, and claim 28 of the '494 patent, the asserted claims remain otherwise valid and are infringed by Teva's ANDA product.

[5] My rulings on the are laid out *infra*, but as a preliminary matter, I deny Tris's motion in limine no. 4 (DE 156 at 13-15) as moot. The evidence relevant to that motion was not introduced at trial and forms no part of my decision (*See* DE 179-1 at 1). In addition, Teva's motion in limine no. 2 was withdrawn (DE 179-2 at 1.) All objections that are not discussed *infra* are immaterial to the result and are deemed to be denied as moot.

May 18, 2022, Judge Kiel issued a final pretrial order (DE 165), and the bench trial began on May 23, 2022. I accepted affidavits in lieu of direct testimony; the bench trial thus consisted of four days of cross and redirect examination of various expert witnesses, and introduction of exhibits. (DE 173, 175, 176, 177.) After the trial concluded, both parties filed opening post-trial briefs on June 27, 2022, and responsive post-trial briefs on July 18, 2022. (DE 197, 199, 201, 204.)

B. ADHD Treatment

ADHD is characterized by a lack of attention, hyperactivity, and impulsivity. It affects millions of children, impairing their ability to perform necessary activities and, vitally, interfering with their performance in school. (PTX-519 ¶ 36–37; DTX-458 ¶ 16.) Counterintuitively, ADHD has long been treated by use of stimulants, most importantly methylphenidate ("MPH"). (PTX-520 ¶ 137; DTX-458 ¶ 17.) Ritalin®, released in 1955, was the first MPH medication. (PTX-520 ¶ 137; DTX-458 ¶ 18.) As originally formulated, Ritalin® and other similar medications were immediate release ("IR") medications, *i.e.*, the MPH they contained was immediately introduced to the patient's bloodstream. (PTX-520 ¶ 138; DTX-458 ¶ 18.) IR formulations featured a quick onset, but lasted only a few hours, and hence required repeated dosing to maintain symptom relief throughout the day. (PTX-520 ¶ 139–41; DTX-458 ¶ 21.) The need for repeated dosing, particularly at school, had obvious drawbacks, which led to the development of extended release ("ER") formulations in the 1980s. (DTX-458 ¶ 21–23.)

The first of these ER products, released in 1982, was Ritalin SR®. (PTX-520 ¶ 143.) Ritalin SR® had a flat pharmacokinetic ("PK") profile with a single mean peak. (*Id.* ¶ 146.) Ritalin SR®, however, was a commercial failure because it turned out that such a profile generally results in acute tolerance, making the drug less effective than immediate release formulations. (*Id.* ¶ 147–50; 157–59.) The search for ER formulations continued, however, and resulted in the ER formulations of Concerta®, Metadate CD®, Focalin XR®, and Ritalin LA®, all released between 2000 and 2005. (DTX-458 ¶ 28.) Having learned from

the failure of Ritalin SR®, the creators of these new drugs avoided a flat PK profile with a single mean peak, and instead opted for a bimodal[6] PK profile which became more pronounced over time. (PTX-520 ¶ 162–65, 225; 2T at 324:23–328:18; *Tris Pharma, Inc. v. Actavis Lab'ys FL, Inc.*, No. 2021-1495, 2022 WL 2525318, at *3 (Fed. Cir. July 7, 2022) (upholding a finding that Concerta is bimodal).)

These four ER medications are all designed to be swallowed in pill form. (PTX-520 ¶ 166, 174, 180, 185.) In addition, for three of them (Metadate CD®, Ritalin LA®, and Focalin XR®, but not Concerta®) it is possible to open the capsule and sprinkle its contents on applesauce to avoid the necessity of swallowing a pill, but this approach has its own drawbacks. (PTX-520 ¶ 206–07; DTX-458 ¶ 57.) In addition, there is Daytrana®, a transdermal patch which delivers MPH to the patient over the course of the day. (PTX-520 ¶ 208–09.) The only ADHD medications available in chewable form were IR formulations such as Methylin Chewable Tablets, which have the same drawbacks as other IR Formulations. (PTX-520 ¶ 140–41; DTX-458 ¶ 58.)

In short, before QuilliChew, the available forms of MPH medications were as follows: There were ER pill formulations designed to be swallowed, and there were chewable IR formulations, but there were not any chewable ER formulations.

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[6] I deny Tris's first and second motions in limine.

Tris's motion in limine no. 1 sought to estop Teva from arguing that Concerta and Metadate CD have a single mean peak PK profile. Although I agree with Tris that both drugs do have a bimodal profile, I find estoppel inappropriate. In this action, I construed the term "single mean peak" in the *Markman* hearing, but that term was not construed in prior proceedings which determined that the other drugs were bimodal. (DE 158 at 3.) In short, I would reject such an argument by Teva, but would not preclude Teva from making it.

Tris's motion in limine no. 2 argued that I should exclude testimony by Teva's experts that Concerta has a single mean peak, because it would allegedly be inconsistent with my claim construction. Again, although I agree in the end that Concerta is bimodal, I do not think that Teva's argument would be strictly inconsistent with the claim construction, and I do not preclude it. (DE 156 at 4–7.)

C. The Asserted Patents and Asserted Claims

Tris alleges that Teva's ANDA product directly infringes nine claims of five separate patents. I review them briefly.

Tris alleges that Teva's ANDA product infringes claims 22 and 24 of the '399 patent, which are both dependent on claim 1 of the '399 patent. Those three claims read as follows:

> 1. An extended release racemic methylphenidate chewable tablet, wherein said chewable tablet is a uniform solid dispersion comprising: a sustained release racemic methylphenidate component comprising a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex in an optional polymeric matrix, wherein said barrier coating is present in an amount of about 20% w/w to about 50% w/w % which provides a sustained release profile to the racemic methylphenidate and is over the racemic methylphenidate-cation exchange resin complex-optional matrix, and wherein when present the polymeric matrix comprises the methylphenidate-cation exchange resin complex and a water-insoluble polymer or copolymer or a water-soluble polymer or copolymer; and at least one immediate release racemic methylphenidate component which provides a release in less than about 30 minutes as determined in an in vitro dissolution assay; wherein about 50% w/w to about 90% w/w of the racemic methylphenidate active component is provided by the sustained release component based on the total amount of racemic methylphenidate in the tablet; wherein said chewable tablet is capable of being divided and providing tablet portions which retain a therapeutically effective extended release profile, and a pharmacokinetic profile in which the methylphenidate has at least one of: a geometric mean for area under the curve $(AUC)_{0-\infty}$ of about 110 ng-hr/mL to about 140 ng-hr/mL or a geometric mean C_{max} of about 10 ng/mL to about 15 ng/mL, under fasted and fed conditions in adults following a single oral administration of a chewable tablet which comprises the equivalent of 40 mg racemic methylphenidate HCl.
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> 22. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the chewable tablet has a pharmacokinetic profile for racemic methylphenidate comprising a single mean plasma concentration peak.
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> 24. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the methylphenidate plasma concentration, as determined under fasted and fed conditions

following a single oral administration of said chewable tablet at a dose equivalent to 40 mg racemic methylphenidate HCl in adults, is equivalent to the plasma concentration curve of FIG. 1 from about 0 to about 8 hours.

(JTX-001 at 31, 33.)

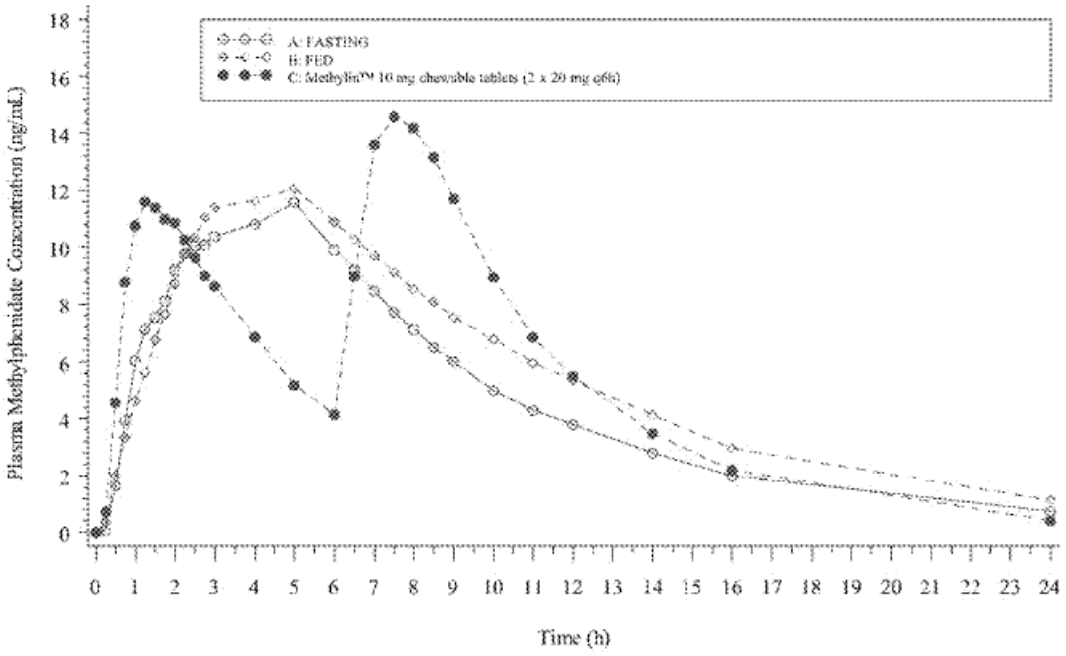

Figure 1 This figure reproduced "Figure 1" from the '399 patent and ’545 patents. (JTX-001_0009; JTX-003_0013.)

Tris alleges that Teva’s ANDA product infringes claim 37 of the ’544 patent, which is dependent on claim 28 of the ’544 patent. Those two claims read as follows:

28. An extended release racemic methylphenidate chewable tablet, wherein said chewable tablet is a uniform solid dispersion comprising: (a) a sustained release, racemic methylphenidate component comprising a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex which comprises: (i) a racemic methylphenidate-cation exchange resin complex comprising racemic methylphenidate and a pharmaceutically acceptable cation ion exchange resin, wherein the racemic methylphenidate is bound to the pharmaceutically acceptable cation exchange resin; (ii) a barrier coating over (i), wherein the barrier coating comprises a

> water-insoluble, water-permeable, pH-independent polymer and a plasticizer and the barrier coating is present in an amount of about 20% w/w to about 50% w/w % based on the weight of the racemic methylphenidate-cation exchange resin complex of (i) and provides a sustained release profile to the racemic methylphenidate; and wherein about 50% w/w to about 90% w/w of the racemic methylphenidate is provided by the sustained release component based on the total amount of racemic methylphenidate in the tablet; and (b) at least one immediate release racemic methylphenidate component which provides a release of the racemic methylphenidate in less than about 30 minutes as determined in an in vitro dissolution assay; wherein said chewable tablet is capable of being divided and providing tablet portions which retain a therapeutically effective extended release profile, and a pharmacokinetic profile in which the methylphenidate has at least one of: a geometric mean for area under the curve $(AUC)_{0-\infty}$ of about 110 ng-hr/mL to about 140 ng-hr/mL or a geometric mean C_{max} of about 10 ng/mL to about 15 ng/mL, under fasted conditions in adults following a single oral administration of a chewable tablet which comprises the equivalent of 40 mg racemic methylphenidate HCl.
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> 37. The tablet according to claim 28, wherein the tablet has a pharmacokinetic profile for racemic methylphenidate which comprises a single mean concentration peak.

(JTX-002 at 32–34.)

Tris alleges that Teva's ANDA product infringes claims 17, 23, 24, and 28 of the '545 patent, which are all dependent on claim 1 of the '545 patent. Those five claims read as follows:

> 1. An extended release racemic methylphenidate chewable tablet, wherein the chewable tablet is a solid dispersion comprising: (a) a sustained release, racemic methylphenidate component comprising a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex which comprises: (i) a racemic methylphenidate-cation exchange resin complex comprising racemic methylphenidate and a pharmaceutically acceptable cation ion exchange resin, wherein the racemic methylphenidate is bound to the pharmaceutically acceptable cation exchange resin; (ii) a water-insoluble, water-permeable, pH-independent, barrier coating comprising cellulose acetate and a plasticizer; wherein the barrier coating provides a sustained release profile to the racemic methylphenidate as defined in (a); and wherein about 50% w/w to about 90% w/w of total

racemic methylphenidate in the chewable tablet is provided by the sustained release component; and (b) an immediate racemic methylphenidate component comprising racemic methylphenidate-cation exchange resin complex which provides a release of the racemic methylphenidate in less than about 30 minutes as determined in an in vitro dissolution assay, wherein the methylphenidate-cation exchange resin complex comprises racemic methylphenidate bound to a pharmaceutically acceptable cation exchange resin; wherein the chewable tablet is capable of being divided and providing tablet portions which retain a therapeutically effective extended release profile, and a pharmacokinetic profile in which the racemic methylphenidate has at least one of: a geometric mean for area under the curve $(AUC)_{0-\infty}$ of about 110 ng-hr/mL to about 140 ng-hr/mL or a geometric mean C_{max} of about 10 ng/mL to about 15 ng/mL, under fasted conditions in adults following a single oral administration of the chewable tablet which has a total amount of racemic methylphenidate which is the equivalent of 40 mg racemic methylphenidate HCl.

17. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the tablet has a pharmacokinetic profile for racemic methylphenidate comprising a single mean plasma concentration peak which is about 4 hours to about 5.25 hours under fasted conditions.

23. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the methylphenidate plasma concentration, as determined under fasting conditions following a single oral administration of said chewable tablet at a dose equivalent to 40 mg racemic methylphenidate HCl in adults under fasting conditions, has the fasting plasma concentration curve of FIG. 1 from about 0 to about 8 hours.

24. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the pharmacokinetic profile for the methylphenidate further comprises an AUC_{0-3} which is bioequivalent to about 18 ng-hr/mL.

28. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein pharmacokinetic profile for methylphenidate further comprises one or more of an AUC_{0-3} of the fasting or fed plasma concentration curve of FIG. 1 or an AUC_{0-4} of the fasting or fed plasma concentration curve of FIG. 1.

(JTX-003 at 31, 33, 34.)

Tris alleges that Teva's ANDA product infringes claim 28 of the '494 patent, which is dependent on claim 26 of the '494 patent. Those two claims read as follows:

> 26. A racemic methylphenidate tablet, wherein the tablet is a uniform solid dispersion comprising: (a) a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex which comprises: (i) a racemic methylphenidate-cation exchange resin complex comprising racemic methylphenidate and a pharmaceutically acceptable cation ion exchange resin, wherein the racemic methylphenidate is bound to the pharmaceutically acceptable cation exchange resin; (ii) a water-insoluble, water-permeable, pH-independent, barrier coating comprising a water-insoluble polymer and a plasticizer over the racemic methylphenidate-cation exchange resin complex of (a)(i), wherein the barrier coating modifies the release of the racemic methylphenidate in the complex; (b) a first immediate release component which comprises an immediate release uncoated racemic methylphenidate-ion exchange resin complex, wherein about 5% to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (b); and (c) a second immediate release racemic methylphenidate component which comprises an uncomplexed racemic methylphenidate, wherein about 5% w/w to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (c); wherein the tablet is capable of being swallowed intact or following being divided or chewed, and wherein the tablet provides a pharmacokinetic profile for racemic methylphenidate comprising a geometric mean area under the curve $(AUC)_{0-\infty}$ of about 10 ng/mL to about 15 ng/mL and/or a single mean plasma concentration peak for racemic methylphenidate, and optionally further comprising a T_{max} of about 4 hours to about 5.25 hours for racemic methylphenidate, under fasted conditions in adults following a single oral administration of the tablet which has a total amount of racemic methylphenidate which is the equivalent of 40 mg racemic methylphenidate HCl.
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> 28. The racemic methylphenidate chewable tablet according to claim 26, wherein the first immediate release component (b) is about 15% w/w of the total racemic methylphenidate in the tablet, the second immediate release component (c) is about 15% w/w of the total racemic methylphenidate in the tablet, or each (b) and (c) are about 15% w/w of the total racemic methylphenidate in the tablet.

(JTX-004 at 35–36.) Teva has stipulated to the infringement of this claim, but argues that this claim is invalid for obviousness.

Finally, Tris alleges that Teva has infringed claim 23 of the '495 patent, which is dependent on claim 21 of the '495 patent. Those two claims read as follows:

> 21. A racemic methylphenidate chewable tablet, wherein the chewable tablet is a uniform solid dispersion comprising: (a) a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate—cation exchange resin complex in an optional matrix, wherein the barrier coating comprises a water-insoluble barrier coating polymer and a plasticizer, which barrier coating is present in an amount of about 10% w/w to about 70% w/w % based on the weight of the precoated racemic methylphenidate—cation exchange resin complex—optional matrix, wherein the barrier coating is over the precoated racemic methylphenidate—cation exchange resin complex—optional matrix and provides a sustained release profile to the racemic methylphenidate in (a), and wherein when present the matrix comprises the racemic methylphenidate—cation exchange resin complex and further comprises a water-insoluble polymer or copolymer or a water-soluble polymer or copolymer; (b) a first immediate release component which comprises an immediate release uncoated racemic methylphenidate—ion exchange resin complex, wherein about 5% w/w to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (b); and (c) a second immediate release racemic methylphenidate component which comprises an uncomplexed racemic methylphenidate, wherein about 5% w/w to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (c); wherein said chewable tablet is capable of being divided and providing tablet portions which retain the release profile for the racemic methylphenidate in the undivided tablet following oral dosing.
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> 23. The racemic methylphenidate chewable tablet according to claim 21, wherein the first immediate release component (b) is about 15% w/w of the total racemic methylphenidate in the tablet and/or the second immediate release component (c) is about 15% w/w of the total racemic methylphenidate in the tablet.

(JTX-005 at 32–33.) Teva has stipulated to the infringement of this claim, but argues that the claim is invalid for obviousness.

The parties have generated a set of PK specifications from the patent claims, which are as follows:

Pharmacokinetic Parameter	**Asserted Claims**
$AUC_{0-\infty}$ of about 110 ng·hr/mL to about 140 ng·hr/ml or a geometric mean C_{max} of about 10 ng/mL to about 15 ng/mL, which, under the construction of "about," is an AUC0-∞ of 99 ng·hr/mL to 154 ng·hr/mL or a geometric mean C_{max} of 9 ng/mL to 16.5 ng/mL.	All asserted claims of the '399, '544, '545, and '494 patents
T_{max} of about 4 hours to about 5.25 hours under fasted conditions, which under the construction of "about," is a T_{max} of 3.6 hours to 5.78 hours	'494 Patent, claim 28
Pharmacokinetic profile for racemic methylphenidate comprising a single mean [plasma] concentration peak	'399 Patent, claim 22; '544 Patent, claim 37; '545 Patent, claim 17; '494 Patent, claim 28
Limitations relating to Figure 1 of the asserted patents ("the Figure 1 Terms"), which have been construed to mean "a plasma concentration curve, when compared to the pharmacokinetic profile of Figure 1, is essentially the same, and absolute identity is not required"	'399 Patent, claim 24; '545 Patent, claims 23, 28
AUC_{0-3} which is bioequivalent to about 18 ng-hr/mL, agreed to by Tris and Teva to mean "between 12.96 ng-hr/mL and 24.75 ng-hr/mL"	'545 Patent, claim 24

D. Claim Construction

On August 25, 2021, after a hearing, I issued a *Markman*[7] patent claim construction opinion and order. (DE 106, 107.) The parties contested the meaning of five separate claim terms. I construed those terms as follows.

First, the parties contested the term "therapeutically effective extended release profile," which appears in claim 1 of the '399 Patent, claim 28 of the '544 Patent, and claim 1 of the '545 Patent. (DE 106 at 5.) I found that this term means "an extended release profile associated with a therapeutic effect that lasts for a period of at least about 12 hours." (*Id.* at 15.)

Second, the parties contested the term "a single mean plasma concentration peak" and "a single mean concentration peak." The first term appears in claim 22 of the '399 Patent and claim 17 of the '545 Patent, while the second term appears in claim 37 of the '544 patent. (*Id.* at 16.) I adopted Tris's construction, construing both terms as "a mean plasma concentration profile with a single peak, but one that need not be a single point." (*Id.* at 22–23.)

Third, the parties contested the meaning of the terms "the [MPH] plasma concentration, as determined under fasted and fed conditions . . . *is equivalent to* the plasma concentration curve of FIG. 1 from about 0 to about 8 hours" ('399 Patent, claim 24); "the [MPH] plasma concentration, as determined under fasting conditions . . . *has* the fasting plasma concentration curve of FIG. 1 from about 0 to about 8 hours" ('545 Patent, claim 23); and "wherein pharmacokinetic profile for [MPH] further *comprises* one or more of an AUC_{0-3} of the fasting or fed plasma concentration curve of FIG. 1 or an AUC_{0-4} of the fasting or fed plasma concentration curve of FIG. 1" ('545 Patent, claim 28). (DE 106 at 24.) The parties agreed that the three *italicized* terms ("is equivalent to," "has," and "comprises") should have the same meaning. (*Id.* at 25.) I found that these three terms meant that "The plasma concentration curve at issue,

[7] See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976–79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

when compared to the pharmacokinetic profile of Figure 1, must be essentially the same, but absolute identity is not required." (*Id.* at 33.)

Fourth, the parties contested the meaning of the term "wherein said barrier coating is present in an amount of about 20% w/w to about 50% w/w," which appears in claim 1 of the '399 patent. (*Id.* at 34.) I found that these terms mean "that the barrier coating is present in an amount of about 20% w/w to about 50% w/w, based on the weight of the pre-coated component." (*Id.* at 38–39.)

Finally, the parties contested the meaning of "pharmacokinetic profile," a term which appears in claims 1 and 22 of the '399 Patent, claims 28 and 37 of the '544 Patent, and claims 1, 17, 24, and 28 of the '545 Patent. (*Id.* at 39.) I construed this term as "a plot of plasma drug concentration over time based on mean data." (*Id.* at 40.)

E. Clinical Trials and Data

Only one clinical trial was ever performed on QuilliChew that measured the effectiveness of the drug.[8] (PTX-519 ¶ 54; 2T at 218:24–220:23.) That clinical study (the "NextWave Study", JTX-034) was performed in support of QuilliChew's New Drug Application to the FDA. (PTX-519 ¶ 54.) The NextWave Study measured QuilliChew's efficacy in a laboratory classroom study of subjects between 6 and 12 years of age. (JTX-195 at 10.) Eighty-five subjects were evaluated during a double-blind treatment period. (*Id.*) Forty-two subjects received QuilliChew and 43 received a placebo. (*Id.*) The trial used the Swanson, Kotkin, Agler, M-Flynn, and Pelham ("SKAMP") behavior rating scale. (JTX-195 at 10; PTX-515 ¶ 43–46.) QuilliChew's label states that "QuilliChew ER also showed improvement over placebo at 0.75, 2, 4, and 8 hours post-dosing." (JTX-195 at 10.) The difference in SKAMP scores between the two groups was found to be statistically significant in relation to a p-value of .05,

[8] Because Teva's ANDA product is bioequivalent to QuilliChew, Teva relied on QuilliChew's clinical study. Teva did, however, perform dissolution studies to determine the PK profile of its ANDA product. (*See* JTX-027.)

which is the FDA's typical efficacy threshold. A p-value under .05 signifies a less than 5% probability that the difference between the two groups' SKAMP scores at 0.75, 2, 4, and 8 hours was attributable to chance. Although the mean SKAMP score of the treatment group was lower than that of the placebo group at 10, 12, and 13 hours as well, that difference was not statistically significant when measured against a p-value of .05. (*Id.*; PTX-519 ¶ 91.) Specifically, at 10 hours, the p-value was 0.133 and at 12 hours the p-value was .206.[9] (JTX-034_0130; 2T at 282:4–283:18; PTX-519 ¶ 118.) Thus, at the 10-hour point, the likelihood that the difference in mean SKAMP scores was attributable to chance was 13.3%, and at the 12-hour point, the likelihood was 20.6%.

QuilliChew's label includes a graph of the SKAMP scores of the treatment and control groups, as well as a table that includes each group's mean pre-dose SKAMP score and each group's least-square mean SKAMP score for the classroom day. (JTX-195 at 9.) That table reveals that the placebo group had a lower mean *pre-dose* SKAMP score than the QuilliChew group—specifically, the placebo group had a mean pre-dose score of 13.8 while the QuilliChew's group had a mean pre-dose score of 17.5. (*Id.*) This discrepancy was likely due to the "rebound effect," meaning that because the treatment group had been taking QuilliChew for two weeks prior to the SKAMP measurement, its members become more hyperactive in the period immediately before taking the drug, and thus scored higher on the SKAMP scale. (2T at 275:21–276:2.)

The SKAMP-Combined Change Score is meant to adjust for that rebound effect—roughly, to calibrate the results to create an apples-to-apples comparison between the two groups. (PTX-519 ¶ 75.) This SKAMP-Combined Change Score measure was used by Dr. Sharon B. Wigal in her 2017 article titled "Efficacy and Safety of a Chewable Methylphenidate Extended-Release

[9] In addition to the SKAMP-Combined Change Scores, discussed *infra*, Dr. McGough also testified that the SKAMP raw scores showed statistically significant effect for male subjects at 10 and 12 hours. (PTX-519 ¶ 107–14.)

Tablet in Children with Attention-Deficit/Hyperactivity Disorder," published in the Journal of Child and Adolescent Psychopharmacology, which analyzed the data from the NextWave Study.[10] (JTX-107.) Wigal found that, measured by the SKAMP-Combined Change Scores, QuilliChew had a statistically significant effect, not only at the earlier times, but at the 10- and 12-hour time points as well. (PTX-519 ¶ 84, 90.) What is more, Wigal found that this effect was not statistically significant merely at a 0.05 p-value. Because she adjusted the SKAMP scores to generate the change scores, Wigal used a "Bonferroni adjustment" p-value of 0.007 and found that the SKAMP change scores were statistically significant at that lower 0.007 p-value up until the 12-hour mark, but at the 13-hour mark, the p-value was just outside that range, at 0.0076. (*Id.* ¶ 90–91; JTX-107 at 7.)

The NextWave Study formed a significant part of the basis for the FDA's approval of QuilliChew in 2015. QuilliChew was then, and remains, the only ER chewable tablet in this market. (PTX-515 ¶ 19.)

F. Prior Art

The parties have agreed that all of the subject patents share a priority date of August 15, 2012. (DE 165 ¶ 23, 29, 35, 41, 47.) The prior art references discussed by the parties in their post-trial briefs are thus prior art for all five patents. Those prior art references are as follows:

- L. Allen et al., Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (8th ed.), 2005 ("Ansel's") (JTX-018 and JTX-060).
- U.S. Patent Application Publication No. 2005/0181050 ("Hirsh") (JTX-016)
- U.S. Patent No. 4,996,047 ("Kelleher") (JTX-059)
- U.S. Patent No. 6,419,960 ("Krishnamurthy") (JTX-066) issued on July 16, 2002

[10] Wigal's co-authors were Ann Childress, Sally A. Berry, Heidi Belden, Faith Walters, Phillip Chappell, Nancy Sherman, John Orazem, and Donna Palumbo.

- U.S. Patent Application No. 2007/0215511 ("Mehta 2007") (JTX-017)
- K. S. Patrick et al., New Methylphenidate Formulations for the Treatment of Attention Deficit/Hyperactivity Disorder, Exp. Opin. Drug. Deliv., 2(1):121–143, 2005 ("Patrick 2005") (JTX-068)
- M. Rochdi et al., Dose-Proportional Pharmacokinetics of a Methylphenidate Extended-Release Capsule, Int. J. Clin. Pharmacol. and Therapeutics, 42(5):285–292, 2004 ("Rochdi") (JTX-103)
- U.S. Patent Application Publication No. 2010/0260844 ("Scicinski") (JTX-022)
- The WHO Drug Information, 25(2):138–147, 2011 ("WHO") (JTX-078)
- Swanson, J. et al., "Acute Tolerance to Methylphenidate in the Treatment of Attention Deficit Hyperactivity Disorder in Children," Clin. Pharmacol. Ther. 66:295-305 (1999) ("Swanson 1999") (JTX-117)
- Swanson et al., "Development of a New Once-a-Day Formulation of Methylphenidate for the Treatment of Attention deficit/Hyperactivity Disorder," Archives of General Psychiatry 60(2):204-211 (2003) ("Swanson 2003") (JTX-115)
- Swanson, J. et al., "A Comparison of Once-Daily Extended-Release Methylphenidate Formulations in Children With Attention-Deficit/Hyperactivity Disorder in the Laboratory School (The Comacs Study)," Pediatrics 113(3):206-216 (March 2004) ("Swanson 2004") (JTX-105)
- The Physician's Desk Reference 65th ed. (2011) ("PDR 2011") (JTX-035)
- The Physician's Desk Reference 61st ed. (2007) ("PDR 2007") (JTX-036)

- Methylin Chewable Tablets®. A racemic methylphenidate hydrochloride immediate-release chewable tablets, which were approved by the FDA in 2003 for the treatment of attention deficit disorders and narcolepsy. Its label was published in 2003. (JTX-014)
- Methylin Oral Solution®. An immediate-release oral solution comprised of racemic methylphenidate HCl, administered two to three times daily. Its label was published in 2002. (JTX-133)
- Patrick, "Evolution of Stimulants to treat ADHD: transdermal methylphenidate," Human Psychopharmacology 24(1):1-17 (2009) ("Patrick 2009") (JTX-101)
- Biederman, "New-Generation Long-Acting Stimulants for the Treatment of Attention-Deficit/Hyperactivity Disorder" (Nov. 2003) ("Biederman") (JTX-102)
- Markowitz et al., "Advances in the Pharmacotherapy of Attention-Deficit Hyperactivity Disorder: Focus on Methylphenidate Formulations," Pharmacotherapy 23(10):1281-1299 (2003) ("Markowitz")
- Concerta® Citizen Petition (JTX-114)
- Gonzalez et al., "Methylphenidate bioavailability from two extended-release formulations," International Journal of Clinical Pharmacology and Therapeutics 40(4):175-184 (2002) ("Gonzalez") (JTX-194)

II. CONCLUSIONS OF LAW

The Hatch-Waxman Act strikes a balance between two competing policy interests: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002). A brand name drug manufacturer seeking FDA approval must

submit an extensive NDA that includes, among other things, a statement of the drug's components, proposed labeling describing the uses for which the drug may be marketed, and scientific data showing that the drug is safe and effective. 21 U.S.C. § 355(b)(1); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). The Hatch-Waxman Act streamlines the FDA approval process for generic manufacturers, who can "bring their products to market without submitting all of the extensive drug and clinical data ordinarily required of an NDA under 21 U.S.C. § 355(b)(1)." *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015). A generic drug applicant seeking approval to market may file either an ANDA or "505(b)(2) application." 21 U.S.C. § 355(b)(2), (j). An ANDA allows generic drug applicants seeking approval "to rely on the safety and efficacy information for an approved drug listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the 'Orange Book.'" *Takeda*, 785 F.3d at 629.

After consulting the Orange Book, a generic company filing an ANDA is required to assure "the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco Pharm. Labs.*, 566 U.S. at 406. To achieve this, a generic manufacturer can file a "paragraph IV certification," which states that a listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The Act deems such a filing to be an act of infringement, affording the branded manufacturer the right to sue immediately.[11] *See* 35 U.S.C. § 271(e)(2)(A). Assuming the brand does so, the FDA may not approve the ANDA until thirty months pass, or until the court finds the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Once invalidity is asserted in a paragraph IV certification, the ANDA applicant takes on the burden of establishing it. *In re Cyclobenzeprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1078

[11] Throughout this Opinion, the term "infringement" is used in this specialized, anticipatory sense.

(Fed. Cir. 2012). A patent and each of its claims are presumed to be valid, even where those claims may be dependent upon other invalid claims in the patent. 35 U.S.C. § 282(a). A party may rebut this presumption of validity only by clear and convincing evidence. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) (citing 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011)).

Once non-infringement is asserted in a paragraph IV certification, the patentee takes on the burden of establishing infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988); *Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997). To prove infringement, the patentee must show that it is more likely than not that the proposed ANDA product would, if commercially marketed, meet the claim limitations of the patent-in-suit. *See Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1287 (Fed. Cir. 2010); *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002).

In its complaint, Tris alleged direct, induced, and contributory infringement. *See* 35 U.S.C. § 271 (a)–(c). At trial and in its post-trial briefing, however, Tris focused solely on direct infringement. Teva denies that its ANDA product infringes seven of the nine asserted claims. It also argues that all of the asserted claims are invalid due to obviousness and that claim 24 of the '399 patent and claims 23 and 28 of the '545 patent (the "Figure 1 Terms") are invalid for indefiniteness.

I discuss the validity issues first, in section II.A. In subsection II.A.1, I make the following invalidity findings: 1) Teva has shown by clear and convincing evidence that claim 24 of the '545 patent is invalid; 2) Teva has shown by clear and convincing evidence that the $AUC_{0-\infty}$ and C_{max} elements incorporated in dependent claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent are invalid for obviousness; 3) Teva has failed to show by clear and convincing evidence that Claim 23 of the '495 patent is invalid. In subsection

II.A.2, I reject the indefiniteness challenge to the Figure 1 Terms. Thus, I find that 1) claim 23 of the '495 patent is fully valid; 2) when shorn of the limitations related to $AUC_{0-\infty}$ and C_{max}, the following claims are valid: claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, and 28 of the '545 patent, and claim 28 of the '494 patent;[12] and 3) claim 24 of the '545 patent is fully invalid.

In section II.B, I consider whether Teva's ANDA product infringes the asserted claims. I find that Tris has established by a preponderance of the evidence that Teva's ANDA product infringes the asserted claims, noting of course that I have already found claim 24 of the '545 patent fully invalid.

A. Validity

Teva argues that the asserted patent claims are invalid. First, it argues that all of the asserted claims are invalid for obviousness. Second, it argues that the Figure 1 Terms are also invalid for indefiniteness.

1. Obviousness

Teva alleges that, as of the priority date, the creation of an extended release chewable MPH tablet conforming to the limitations of the asserted claims would already have been obvious to a person of ordinary skill in the art ("POSA") under 35 U.S.C. § 103. Teva's burden here, as in other validity challenges, is proof by clear and convincing evidence. *See* pp. 18–19, *supra*. The parties agree that August 15, 2012, is the priority date for the prior art analysis. Teva asserts that, as of that date, a POSA familiar with the prior art would have been motivated to create a chewable and divisible MPH tablet with the PK characteristics claimed in the asserted patents, and would have had a reasonable expectation of success in doing so because the inventions claimed by Tris "are no more than combinations of known elements in the art for their known functions with predictable results." (Def. Br. at 22.)

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[12] Again, the $AUC_{0-\infty}$ and C_{max} elements of these claims, asserted in independent claims, are incorporated in the associated dependent claims, which I have generally found otherwise valid.

A patent claim is invalid as "obvious" where the "differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. A finding of "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (citing *In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985) ("Although [the inventor] declared that it cannot be predicted how any candidate will work in a detergent composition, but that it must be tested, this does not overcome [the prior art's] teaching that hydrated zeolites will work.")).

Four factors guide the obviousness inquiry under § 103: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the field of the invention; and (4) objective considerations such as commercial success, long felt need, and the failure of others to develop the invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). The evidence at trial focused on 1, 2, and 4, the prior-art and objective-considerations factors.[13]

"Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination. Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Unigene Lab'ys, Inc. v. Apotex, Inc.*,

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[13] The parties devote little attention to factor 3, the level of skill possessed by a POSA. Teva defines the POSA as someone who "would have worked as part of a team with training and experience in at least three scientific disciplines (1) clinical treatment of ADHD; (2) PK; and (3) pharmaceutical formulation." (Def. Br. at 22.) Tris does not challenge this definition, so I accept it.

655 F.3d 1352, 1360 (Fed. Cir. 2011) (citation omitted). Importantly, when conducting this analysis, courts must avoid the temptations of hindsight—many inventions appear obvious once they have been invented. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1070–71 (Fed. Cir. 2012).

Teva argues that the asserted claims would be obvious to a POSA because the scope and content of the prior art teaches all claimed elements of the patents-in-suit. Tris, in contrast, argues that the prior art actually taught away from the creation of an ER chewable tablet, and that Teva relies on a number of disparate prior art references whose combination is obvious only in hindsight.

As a preliminary matter, the parties agree that, generally speaking, a POSA would have been motivated to develop a chewable ER MPH medication. Many children are unable or unwilling to swallow pills, limiting the number of ER medications available to them. (Pl. Br. at 5; Def. Br. at 2.) So it is obviousness, not the need or motivation for the invention *per se*, that is at issue.

I begin with an overall discussion of whether the prior art made the means of creating an ER chewable tablet obvious. (Section II.A.1.a.) Then, because this case involves a wide variety of prior art references combined in a number of ways, I proceed more specifically claim by claim, examining whether the prior art made each claim or group of related claims obvious. For each, I begin by recounting the position of Teva and then analyze whether Teva has met its burden of persuasion. (Section II.A.1.b, c, & d). I conclude with an overall discussion of certain objective factors that bear on obviousness. (Section II.A.1.e).

a. It was not obvious to create an ER chewable tablet (relevant to all asserted claims)

As of the priority date in August 2012, there were multiple ER formulations of MPH and chewable IR MPH formulations. There was not, however, an existing chewable ER formulation. The question is whether a POSA

would have found it obvious to create a chewable ER formulation based on the prior art.

Teva acknowledges that a chewable ER formulation was not disclosed in any single prior art reference (3T at 461:5–7), but argues that a chewable ER formulation was obvious based primarily on four pieces of prior art: Mehta 2007, Hirsh, Kelleher, and Scicinski. (Def. Br. at 25–27). Tris responds that those prior art references, singly or in combination, did not teach an ER chewable tablet and that, in fact, the prior art taught away from a chewable ER formulation. (Pl. Br. at 24.) I first discuss Teva's interpretation of the prior art, and then Tris's.

According to Teva, by the priority date, "multiple researchers had disclosed approaches to formulating chewable extended-release products and suggested their use with methylphenidate." (Def. Br. at 25.) As noted, Teva is referring here to Mehta 2007, Hirsh, Kelleher, and Scicinski

First, Teva discusses Mehta 2007, which, it claims, "teaches a POSA how to formulate an extended-release methylphenidate formulation that could withstand chewing and provides the POSA with a reasonable expectation of success that an extended-release chewable tablet can be achieved." (*Id.*) Specifically, Mehta 2007 teaches the use of barrier coatings to create a "highly flexible, substantially tack-free, non-ionic, water-insoluble, water-permeable diffusion membrane which is preferably aqueous-based." (JTX-017 at [0010].) Dr. Elder testified that "[b]ased on the disclosures in Mehta 2007, a POSA would have known that the disclosed coated and uncoated ion-exchange resin complexes would have been compatible with a chewable tablet formulation." (DTX-462 ¶ 81.) Dr. Elder points specifically to the disclosure in Mehta 2007 that the coating "maintains its film integrity even when subjected to severe physical force and stress such as during a compression step in a tabletting machine or the grinding action of a coffee beans grinder, mill, etc." (JTX-017 at [0024].) Mehta 2007, however, does not specifically disclose a *chewable* tablet formulation; indeed, it seems to state that the purpose of the barrier film is to resist chewing, *i.e.,* to "reduce the ability of the subjects to get instant 'high' by

making it more difficult to break the barrier coating by chewing or other mechanical means due to the increased resistance of such flexible coating to easy rupture." (*Id.* at [0013].) Dr. Elder attempted to meet this objection, however, by explaining that a "POSA would have further understood that the role of a barrier coating in abuse deterrence is not mutually exclusive with its ability to be chewed without compromising the release profile of the formulation." (DTX-462 ¶ 84.) Even assuming that is so, to say that the two are not "mutually exclusive" does not really take us very far. What remains unclear is whether or how the technology that worked to deter abuse *via* physical grinding would nevertheless enable a formulation to function effectively when chewed.

Teva's strongest argument related to Mehta 2007 is somewhat indirect; it focuses on a 2010 four-paragraph Tris press release promoting Tussionex, a time-release cough medicine. (DTX-116.) That press release referred to patent pending technology and stated that "Tris pioneered the delivery of taste-neutral, extended release dosage forms such as liquids, ODT/*chewable tablets*, and strips that are traditionally associated with immediate release."[14] (*Id.* (emphasis added).) Reading this Tussionex press release, says Teva, a POSA would have learned that Tris had formulated a taste-neutral chewable tablet in 2010, before the priority date. Teva asserts that the unnamed pending patent referred to in the press releases and news articles was Mehta 2007. (Def. Br. at 34.) The press release, however, relates to a cough medicine; simply includes "chewable tablets" in a generic list that also includes ER liquids and strips; does not specify what "chewable tablets" it is referring to; does not refer to MPH or ADHD; and does not mention Mehta 2007 at all.

[14] Teva also cites two other short news articles from 2009 about Tris's OralXR extended-release technology that refer to "chewable tablets." (DTX-078; DTX-082.) Tris has objected to DTX-082 as hearsay, but I find that the statements are party-opponent statements that were authenticated by Mr. Mehta at trial. *See* Fed. R. Evid. 801(d)(2). (Tris had previously objected to DTX-078 but withdrew that objection. (DE 205 at 1).)

Second, Teva discusses Hirsh, a patent application which disclosed a chewable tablet formulation. (JTX-016 at [0010]–[0018].) Chewability as such is of course not novel, and Hirsh's tablet formulation does involve an ER as well as an IR component.[15] Hirsh, however, includes no dissolution or other PK data demonstrating that its formulation would be medically effective if chewed.

Third, Teva discusses Kelleher, an issued patent, which describes ER ion exchange resin complexes and discloses a chewable tablet. (JTX-059 at 1:54–60, 19:16–34.) Kelleher, however, makes no reference to ADHD or MPH. Unlike Hirsh, Kelleher includes some dissolution data, but only measured for a period of six hours or less for all formulations, and there are no separate dissolution data for a chewed tablet. (JTX-059 at 9:6–18:47; 3T at 597:7–8.)

Fourth, Teva briefly discusses Scicinski, another patent application.[16] Teva claims that Scicinski's target profile was "intended for an abuse-resistant extended-release oral formulation of methylphenidate that would maintain its extended-release properties even 'upon chewing.'" (Def. Br. at 31; JTX-022 at [0170].) On the one hand, Scicinski states that "the carrier system is characterized by the absence of any significant effect on absorption of the methylphenidate from the dosage form … upon chewing." (JTX-022 at [0170]). On the other hand, however, Scicinski is clear that the formulation should be swallowed whole, not chewed, and that the abuse-resistant features relate to prevention of "dose dumping," not to the timed-release effectiveness of the medication. (*Id.* at [0170], [0287]; PTX-518 ¶198–99.)

I move on to discuss Tris's competing interpretation of the prior art. In general, I find Tris's interpretation to be more consonant with the prior art and therefore more convincing.

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15 Teva asserts that Hirsh contemplated using two IR components, but that is not accurate, as discussed *infra*.

16 Scicinski is primarily discussed with regard to a target PK profile, but Teva also discusses it in relation to an ER chewable formulation. (Def. Br. at 31.)

Tris argues that, far from rendering an ER chewable tablet obvious, this prior art taught away from such a formulation. (Pl. Br. at 23–25.) That position I cannot fully accept.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Tris argues convincingly from prior art that an ER chewable tablet of MPH did not exist. (*Id.* at 23; PTX-520 ¶ 220; PTX-516 ¶ 224–26.) The existing oral ER medications for ADHD universally contained instructions not to chew or crush them because doing so would interfere with the ER mechanism. (PTX-516 ¶ 225.) Accordingly, sources such as Ansel's stated that "[p]atients should be advised that modified-release tablets and capsules should not be crushed or chewed, since such action compromises their drug release features." (JTX-018 at 49; *see also* PTX-158 at 2.) It is uncontested that that 2005 statement in Ansel's was accurate in relation to then-existing ER drugs for ADHD, and that those drugs included such warnings in their labels. (*E.g.*, JTX-035_0004 (Concerta).)

A POSA reading Ansel's, then, would surely conclude that then-current ER formulations were not meant to be chewed at all. Whether the prior art teaches away from developing an ER chewable formulation, however, is a distinct question. Neither Ansel's, nor any other piece of prior art, stated that creating an effective chewable ER formulation was impossible, inadvisable, or undesirable. Indeed, it is possible that a POSA who read such prior art could perceive an unmet need and be inspired to attempt to create a chewable ER medication. To be sure, the prior art clearly indicated that existing ER formulations were incompatible with chewing and, in general, served to make the creation of an ER chewable formulation less obvious. I do not go so far,

however, as to find that the prior art taught away from creating an ER chewable tablet in the sense, for example, of misdirecting a POSA.

Tris next challenges Teva's interpretations of Mehta 2007, Hirsh, Kelleher, and Scicinski. I find Tris's interpretation more persuasive.

First, regarding Mehta 2007, Tris correctly points out that a chewable tablet is not among the solid dosage formulations included in that reference. (Pl. Br. at 26; Pl. Response at 31.) It is true that Mehta 2007 disclosed some abuse deterrent properties that would potentially allow the product to be chewed without giving the patient an instant high. There is a long distance, however, between formulating a drug where chewing does not result in "dose dumping" and formulating an extended-release drug that is fully effective when chewed. The language of Mehta 2007 supports this conclusion. Although it undoubtedly discloses an advance in abuse-deterrent technology, the patent states that it "can *reduce* the ability of the subjects to get instant 'high' by making it *more difficult* to break the barrier coating by chewing." (JTX-017 at [0013].) A technology that makes it more difficult to get high is not the same as an efficacious ER chewable tablet. Moreover, Mehta 2007 provides no data demonstrating that the drug, even if chewed, would retain the same PK profile that it had when swallowed. (*Id.*; PTX-516 ¶ 258, 265.)

Tris also argues that the press releases cited by Teva do not help its case because (a) a POSA would not have known that Mehta 2007 was the unnamed patent to which the release referred; and (b) would not have believed that a cursory reference to a "chewable tablet" in relation to non-ADHD medications pointed the way to an ER chewable MPH tablet. (Pl. Response at 31–32; PTX-516 ¶ 252.) I agree. Teva provides no specific evidence that a POSA would understand that the press releases referred to Mehta 2007. Teva fails to persuade the Court that these press releases—a notoriously unreliable genre with little scientific standing—would have appeared to a POSA as the announcement of a major scientific advancement in ER technology. I therefore find that these press releases do nothing to make the creation of an ER chewable tablet of MPH obvious.

As to Hirsh and Kelleher, Tris argues that a POSA would not have taken these references at face value because they did not include any dissolution data proving that they work. (Pl. Br. at 27–28.) Again, I agree.

There was a background assumption, widely present in the literature, that an extended release medication should not be chewed or crushed. That background assumption would lead a POSA to be cautious about believing backdoor or offhand assertions that a chewable ER formulation had been invented—especially when there were no data to demonstrate that the formulation worked effectively to administer a dose over time in the desired manner. True, I have already found that the prior literature did not literally teach away from developing an ER chewable tablet; it did, however, clearly teach that existing ER formulations could not and should not be chewed. A POSA would thus be skeptical of data-free claims that a chewable ER formulation had been invented. Absent any data to show that Hirsh or Kelleher's formulation was effective, a POSA would not have found it obvious to develop an ER chewable tablet for MPH.

Finally, Tris argues that Scicinski does not disclose a chewable tablet, but rather states that the formulation, though it has abuse deterrent properties, should be swallowed whole. (Pl. Response at 31; JTX-022 at [0170].) I agree with Tris's reading and find that Scicinski does not disclose a chewable tablet. As stated above, I find that abuse deterrent properties that prevent dose-dumping through chewing would not teach a POSA that a medication would be equally effective when chewed and thus make obvious the means to develop an ER chewable tablet.

I consider the references in combination. Overall, I find that the literature, such an Ansel's, taught that ER formulations generally could not be chewed or crushed while maintaining their effectiveness, and in many cases taught that they should not be chewed. I find that Mehta 2007 and Scicinski do not disclose an ER chewable tablet, and that the abuse-resistant properties that they do disclose would not lead a POSA to believe that an effective ER chewable tablet was obvious. I find that although the press releases do mention

an ER chewable tablet (without specifying its nature), a POSA would not take unverified, data-free assertions in a short press release at face value. Finally, I find that although Hirsh and Kelleher do disclose an ER chewable tablet, a POSA would not have accepted these data-free claims where the prior art had broadly stated that ER formulations should not be chewed. Finally, insofar as the prior art did disclose different elements that could be combined to create an ER chewable tablet, I find that Tris has provided no evidence that a POSA would be motivated to combine these disparate prior art references. In short, the prior art as of August 15, 2012, did not add up to make the development of an ER chewable tablet of MPH obvious.

The preceding discussion has been somewhat of a general overview. I move on to discuss more specifically the obviousness issue in relation to the particular patent claims regarding the manner in which a chewable ER MPH tablet could be created.

b. The use of two distinct IR MPH components together with one ER MPH component was not obvious (relevant to '494 claim 28, '495 claim 23)

Claim 28 of the '494 patent (dependent on claim 26) and claim 23 of the '495 patent (dependent on claim 21) both contain limitations that describe a chewable tablet with two distinct IR components. They describe a tablet "wherein the barrier coating modifies the release of the racemic methylphenidate in the complex; (b) a first immediate release component which comprises an immediate release uncoated racemic methylphenidate-ion exchange resin complex, wherein about 5% to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (b); and (c) a second immediate release racemic methylphenidate component which comprises an uncomplexed racemic methylphenidate, wherein about 5% w/w to about 20% w/w of the total racemic methylphenidate in the tablet is provided by (c)." (JTX-004 at 35:21–30; JTX-005 at 33:13–22.) The effect of this dual IR formulation is to permit the initial therapeutic effect of the drug to be felt quickly, while delaying the remainder, since uncomplexed MPH is absorbed more quickly

than complexed MPH. (PTX-514 ¶ 44.) Thereafter, the ER component becomes dominant.

It is uncontested that no ADHD medication prior to QuilliChew used two IR components and one ER component. (PTX-516 ¶ 276.) Teva, however, argues that the use of two IR components and one ER component was obvious in light of prior art references. First, Teva argues that Hirsh taught the use of three different components (Def. Br. at 37). Second, Teva argues that Concerta had three MPH components. (*Id.*) Third Teva argues that Mehta 2007 "taught that one desirable form of an IR component included methylphenidate bound to an ion-exchanged resin (complexed IR)." (Def. Response at 23.)[17] Generally, however, Teva relies on the argument that a POSA would know that uncomplexed MPH would absorb most quickly (in around 10 minutes) and therefore would be motivated to vary ratios to obtain the desired effect. The bitterness of uncomplexed MPH could simply be masked with a sweetener. (Def. Br. at 38–39 (citing Krishnamurthy).)

Examining the prior art, however, reveals that none of it truly teaches the use of two different IR components. Teva's expert Dr. Elder testified that a POSA would rely on the teachings of Hirsh "for guidance on including more than one immediate-release component[]." (DTX-462 ¶ 213.) Dr. Elder also stated that "Hirsh taught the combination of three different release components to further customize drug release, and suggested the combination of uncomplexed drug with drug-resin complexes." (*Id.* ¶ 104.) Neither of Dr. Elder's interpretations, however, arises from what Hirsh actually says. Hirsh does contemplate using three components, but unambiguously states that the combination is *one* IR component with *two* ER components: "In order to create a final dosage form with three pulses, *an* immediate release dose of drug (e.g., unmodified drug,[18] uncoated drug-resin particles, mucoadhesive *or* taste

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[17] I set aside Teva's reference to a 1985 article by Leeson (Def. Br. at 38) which is not one of Teva's prior art references and which in any event does not teach the use of two IR components and one ER component.

[18] *I.e.*, uncomplexed MPH.

masking coated drug-resin particles) can be combined with enteric coated drug-resin particles and delayed release coated drug resin particles." (JTX-016 at [0078] (emphasis added).) Hirsh thus contemplates using a single IR component and gives several possible alternatives, including uncomplexed MPH and uncoated drug-resin particles. Hirsh describes this IR component as being combined with two ER components, "enteric coated drug-resin particles and delayed release coated drug resin particles" to create three pulses, only one of which is immediate. (*Id.*) In short, Hirsh relies on a single IR component to achieve the fast onset of therapeutic effect, and has not hit upon the idea of exploiting the delay in absorption of complexed versus uncomplexed MPH. In contrast, the claims asserted here describe an outer, immediate release coating that contains two different components, complexed and uncomplexed MPH. Both of those components begin to be absorbed immediately, but the uncomplexed MPH is absorbed more quickly. The combination of the two IR components speeds the initial onset of therapeutic effect and increases the slope of the initial ascent of the PK profile. Then, as the two IR components achieve absorption, the single ER component kicks in, providing a therapeutic effect for many more hours. Contrary to Dr. Elder's claim, then, Hirsh does not teach this use of the two IR components and therefore does not make the use of two IR components in the asserted claims obvious.

Teva's second argument is based on the cross-examination of Dr. McGough. (Def. Br. at 37 (citing 4T at 707:1–709:3).) According to Teva, Dr. McGough admitted that a prior medication, Concerta, has three components: "(1) an outer coating that provides truly immediate release into the patient; (2) a first push that starts to release *immediately*, but is more gradual than the outer coating; and (3) a second push that provides a more extended release of the methylphenidate." (Def. Br. at 37 (emphasis added).) The transcript, however, reveals that this description of Dr. McGough's testimony is inaccurate, in that McGough never claimed that the first push started "immediately." The only IR component mentioned during the questioning was the outer coating. (4T at 707:5–707:11.) Even if Dr. McGough's testimony could

be interpreted to state that Concerta has two IR components (and I do not believe it can), this claim would be directly at odds with the literature that describes Concerta as having a single IR component and two ER components. (JTX-035 at 7; JTX-022 at [0051]–[0052]; PTX-516 ¶ 229.) That a drug's components are three in number would not make it obvious to formulate a new drug differently, using two IR and only one ER component in the manner claimed here.

Finally, Teva argues that Mehta 2007 teaches the use of two IR components and one ER component. (Def. Br. at 37.) In support, it cites Dr. Elder's opinion that "Mehta 2007 also discloses combining uncoated ion exchange resin complex with coated ion exchange resin complex in a formulation to achieve the desired balance of early onset and extended-release." (DTX-462 ¶ 163) (citing JTX-017 at 0072–0073, Ex. 4).) This example, however, unambiguously discloses two, not three, components. To meet this objection, Teva supplements its discussion of Mehta 2007 with a citation to claim 22 of Mehta 2012, a patent. Mehta 2012, however, was not one of Teva's prior art references and was not referenced in Dr. Elder's initial invalidity testimony. Because it was not disclosed by Dr. Elder, Mehta 2012 will not be considered as prior art.[19] But even if Teva were permitted to shoehorn Mehta 2012 to shed light on the meaning of Mehta 2007, I would find it inapposite. Mehta 2012 cannot be said to explain or elucidate the clear language of Mehta 2007, which refers only to two components, one IR and one ER.[20] I thus conclude that Mehta 2007 does not teach the use of two IR components and one ER component, let alone use of them in the manner claimed here.

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[19] Teva argues that Mehta 2012 is prior art because "it issued prior to the earliest priority date of the asserted patents and is from a different inventive entity than the asserted patents." (Def. Br. at 35n.19.) I disagree. Not only was Mehta 2012 not listed as a prior art reference for obviousness, but the Teva's last-minute use of Mehta 2012 in the obviousness context deprived Tris of an opportunity to argue that Mehta 2012 was not, in fact, created by a "different inventive entity" than the asserted patents.

[20] Teva makes no reference to Mehta 2012 in its responsive brief.

Without apposite prior art, Teva is left to argue that a POSA would nevertheless logically infer that using two IR components, including uncomplexed MPH, would lead to a quick acting drug. (Def. Response at 23–24.) But Teva does not explain why, for example, a POSA would choose to use two IR components rather than increase the proportion of a single IR component, as Dr. Mehta testified was standard practice. (PTX-514 ¶ 44.) Teva's meandering path from the prior art to the asserted claim is an example of impermissible hindsight that cannot meet Teva's burden to prove obviousness. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.")

Because no prior art, alone or in combination, teaches or would lead a POSA to infer the use of two IR components in combination with a single ER component, those portions of '494 patent claim 28 and '495 patent claim 23 were not obvious.

c. It was not obvious to use a 15/15/70 ratio of IR to ER components (relevant to '494 claim 28 and '495 claim 23).

Claim 28 of the '494 patent and claim 23 of the '495 patent also claim a particular ratio of IR and ER components (15 IR1, 15 IR2, 70 ER). Teva argues that these claims are invalid for obviousness because the ratio could have been reached through routine optimization (Def. Br. at 43–44) and because the overall IR:ER ratio of 30:70 was used by previous drugs, specifically Metadate CD. (*Id.* at 43). In its responsive brief, Teva argues that the ratio of components "contributes nothing non-obvious to the claim." (Def. Response at 24.) It is perhaps true that *if* a POSA had decided to use two IR components, it would be obvious to aim for the rough 30:70 ratio of IR to ER components used in prior

medications.[21] As I found in the preceding section, however, the use of two IR components was not obvious in the first place. It thus follows that a particular ratio of two IR components in relation to one ER component could not have been obvious.

d. It was obvious to target the claimed ranges for AUC_{0-3}, $AUC0-_{\infty}$ and C_{max} but it was not obvious to target a single mean peak or the asserted combination of parameters (relevant to various claims, listed within)

Finally, as to QuilliChew's PK profile, I find that certain aspects would have been obvious to a POSA, but that others would not. I break down this discussion into four parts: the $AUC_{0-3;}$ the single mean peak; Figure 1; and the combination of parameters.

***AUC_{0-3}* (relevant to '545 patent claim 24).** This limitation refers to the total amount of drug delivered into a patient's bloodstream in the first three hours.[22] This parameter is important because it determines how quickly the drug will begin to affect the patient, and some ADHD medications had been deemed less effective because of delayed onset of action. (*See* PTX-520 ¶ 149–50; DTX-460 ¶ 58–59.) This limitation is related to claim 24 of the '545 patent, which claims an ER chewable tablet wherein "the pharmacokinetic profile for the methylphenidate further comprises an AUC_{0-3} which is bioequivalent to about 18 ng-hr/mL." (JTX-003 at 33.) The parties have construed bioequivalent to "about" 18 ng-hr/mL as encompassing values "between 12.96 ng-hr/mL and 24.75 ng-hr/mL." (PTX-518_0064.) The question then, is whether the prior art teaches a POSA that it was obvious to target an AUC_{0-3} of between 12.96 ng-hr/mL and 24.75 ng-hr/mL. I find that it was obvious.

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[21] Teva does not cite prior art to explain why 15/15/70 would have been more obvious than other ratios in which the IR components added up to 30—say, 10/20/70 or 5/25/70. Normal experimentation or optimization, however, might reasonably have led to the 15-15 option.

[22] AUC stands for the calculus concept of "area under the curve." AUC is what is calculated when an integral of a function is taken across a range, in this case from 0 hours to 3 hours.

Teva argues that a "POSA would have been motivated to arrive at an AUC_{0-3} that is between 9.4 ng·hr/mL and 13.6 ng·hr/mL." (Def. Br. at 30.) This range (barely) overlaps with the claimed range. Teva's expert, Dr. Forrest, opined that a POSA would target the AUC_{0-3} ranges of Metadate CD and Ritalin LA because they had a fast onset of action; Metadate CD's AUC_{0-3} is 9.4 ng-hr/mL, while Ritalin LA's is 13.6 ng-hr/mL.[23] (DTX-460 ¶ 86.) Both values are based on a 20mg dose. Tris points out, however, that its own AUC_{0-3} is based on a 40mg dose, and argues that Dr. Forrest erred by failing to normalize (double) the AUC_{0-3} of Metadate CD and Ritalin LA before drawing any comparison. When normalized, says Tris, the AUC_{0-3} of Ritalin LA is 27.2 ng-hr/mL, well outside of the claimed range of 12.96 to 24.75 ng-hr/mL. (Pl. Response at 29.) I agree with Tris that normalization is the appropriate methodology, as far as that goes. The problem with this argument for Tris, as Teva points out (Def. Response at 29), is that what's good for the goose must be good for the gander. If the appropriate method is to normalize (double) the AUC_{0-3} of the 20mg dose of Ritalin LA, then the AUC_{0-3} of Metadate CD must be normalized as well. When doubled, Metadate CD's AUC_{0-3} is 18.8 ng-hr/mL, near the center of the claimed range.[24]

The question, then, boils down to this: whether a POSA would have targeted the AUC_{0-3} of Metadate CD. I find that the prior art taught a POSA to seek a rapid onset of action, like that of Metadate CD. (PTX-520 ¶ 136, 142–51, 164.) Here, Concerta provides an illustrative contrast; though an extremely popular medication, Concerta "is known to have a delayed onset of effect compared to other second-generation methylphenidate products" including Metadate CD and Ritalin LA, which were created after Concerta and aimed to achieve faster onset of effect. (*Id.* ¶ 173, 179, 184.)

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[23] I deny Tris's motion in limine no. 5. (DE 156 at 17–20.) I find that the relevant combinations of prior art included in Dr. Forrest's testimony were properly disclosed in his opening reports and are therefore properly considered by the Court.

[24] Thus, Dr. Forrest's target range, normalized, would have been between 18.8 ng-hr/mL and 27.2 ng-hr/mL.

Aside from its invocation of normalization, Tris makes no other argument that targeting the AUC_{0-3} range is not obvious. I thus find that a POSA would have been motivated by the prior art to target a range for AUC_{0-3} that largely overlaps with QuilliChew's AUC_{0-3}. And the POSA would have had a reasonable expectation of success in targeting this range; routine optimization by increasing the IR component of the medication would predictably have led to the desired AUC_{0-3}. Importantly, a POSA would not need to anticipate the use of two different IR components (*see* preceding section) to achieve the desired AUC_{0-3}. As noted above, both Metadate CD and Ritalin LA, which have only a single IR component, illustrate the desired AUC_{0-3} range. I therefore find that the AUC_{0-3} range claimed in claim 24 of the '545 patent is invalid for obviousness.

***$AUC_{0-\infty}$ and C_{max}* (relevant to '399 patent claims 22 and 24; '544 patent claim 37; '545 patent claims 17, 23, 24, and 28; '494 patent claim 28)**. The claimed range of $AUC_{0-\infty}$ in the asserted claims is 99 ng-hr/mL to 154 ng-hr/mL and the claimed range of the C_{max} is 9 ng/mL to 16.5 ng/mL. Those claimed ranges, I find, are invalid for obviousness.

Teva argues that based on already-successful products, a POSA would have targeted an $AUC_{0-\infty}$ range of 79.48±23.50 to 106.24±48.04 and a C_{max} range of 4.45 ±1.62 ng/mL to 16.8 ±5.1 ng/mL.[25] (Def. Br. at 29–30.) Teva's expert, Dr. Forrest, calculated these ranges by normalizing the parameters of previously available medications to a 40mg dose and making the smallest result the bottom of the range and the largest result the top of the range. (DTX-460 ¶ 76, 80.) This method, especially when the statistical standard deviation is applied, leads to extremely wide ranges. Teva then claims that *any* overlap between its constructed ranges and the claimed ranges makes the claimed ranges *prima facie* obvious. (Def. Br. at 30 (citing *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006–07 (Fed. Cir. 2018).)

[25] Teva includes the standard deviation in its ranges.

Tris does not dispute that the claimed ranges fall within the ranges that Dr. Forrest constructed, but disputes the validity or relevance of Dr. Forrest's ranges. A POSA, says Tris, would not have mixed, matched, and aggregated parameters from different drugs, but rather would have attempted to recreate the PK parameters of existing drugs, one at a time. (Pl. Br. at 40.) What is more, even if a POSA would be motivated to mix and match, there is still no reason, other than hindsight, that a POSA would have targeted the parameters from the asserted claims. (*Id.*)

Although it is a close question, I find that because the C_{max} and $AUC_{0-\infty}$ fall within the ranges of some preexisting medications (even without mixing and matching), it would have been obvious to a POSA to target these parameters when creating a PK profile. Importantly, then-existing individual drugs, including Concerta and Metadate CD, had *both* C_{max} and $AUC_{0-\infty}$ that fell within the claimed range. (3T 625:23–626:22, 638:17–641:4.) Thus, a POSA had forward-looking reasons, independent of hindsight, to target ranges similar to those claimed. Because the PK ranges of previous medications overlap with the claimed ranges, I find that Teva has made a prima facie case of obviousness. *In re Peterson*, 315 F.3d at 1329. I also find that Tris has not demonstrated that prior art taught away from these $AUC_{0-\infty}$ and C_{max} parameters, or that adoption of them generated unexpected results. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).

In sum, I find that it was obvious for a POSA to target the $AUC_{0-\infty}$ and C_{max} ranges of preexisting drugs, that a POSA would have had a reasonable expectation of success in achieving the targeted ranges, and that these ranges had significant overlap with the claimed ranges. The $AUC_{0-\infty}$ and C_{max} elements, as noted above, are found in independent claims of the patents. I find that the $AUC_{0-\infty}$ and C_{max} elements are invalid as obvious, insofar as they are incorporated in the following asserted dependent claims: claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent.

Single Mean Peak **(relevant to '399 patent claim 22, '544 patent claim 37)**. I find that it was not obvious to a POSA to create a PK profile with a single mean peak. This limitation relates to claim 22 of the '399 patent and claim 37 of the '544 patent. In my *Markman* ruling, I construed single mean peak to mean "a mean plasma concentration profile with a single peak, but one that need not be a single point." (DE 106 at 22–23.) I find that the prior art would have encouraged a POSA to target a bimodal profile rather than a single mean peak, and that the clear trend in the art in the years preceding the priority date was toward increasingly bimodal profiles.

Teva argues that the prior art did not teach away from a single mean peak, that both Concerta and Scicinski taught a single mean peak, and that a POSA would have been motivated to use a single mean peak to avoid the reemergence of symptoms.[26] (Def. Br. at 28, 45–46.) Tris, in contrast, argues that neither Concerta nor Scicinski teaches a single mean peak; that, in fact, all second-generation oral ER medications employed a bimodal profile; and that there is no evidence that reemergence of symptoms was a problem for bimodal ER MPH medications. (Pl. Br. at 38–44.)

As discussed in Section I.B., *supra*, I find that Concerta has a bimodal profile. The profile is concededly less dramatically bimodal than that of some other drugs, such as Focalin XR. Nevertheless, the scientific literature and other courts have found that Concerta is bimodal, and I agree. Concerta's profile has two distinct changes in slope between hours 2 and 5, and I consider that such a profile does not constitute a single mean peak within my construction. This interpretation is shared by the literature, which universally describes Concerta as having a bimodal profile. (PTX-520 ¶169–72 (citing Citizen's petition and Gonzalez; PTX-518 ¶ 161 (citing Patrick 2005 and Patrick

[26] Teva also argues that Daytrana teaches a single mean peak. (Def. Br. at 46.) I find, however, that because Daytrana is a transdermal patch and not an oral formulation it functions differently and thus it is not particularly relevant as prior art.

2009).)[27] Most recently, the Federal Circuit upheld a finding by the United States District Court for the District of Delaware that Concerta was bimodal. *Tris Pharma, Inc. v. Actavis Lab'ys FL, Inc.*, No. 2021-1495, 2022 WL 2525318, at *3 (Fed. Cir. July 7, 2022).

Next, I find that Scicinski would not lead a POSA to target a PK profile with a single mean peak. Whether Scicinski discloses a single mean peak is a close question, but one it is not necessary to answer. I agree with the Federal Circuit and the United States District Court for the District of Delaware that a POSA would not have credited Scicinski's target profile because it was purely aspirational and not supported by experimental data. *Tris v. Actavis*, 2022 WL 2525318, at *5. Thus, even if a POSA did understand Scicinski as having disclosed a single mean peak PK profile, the POSA would not have reason to believe, without experimental evidence, that such a profile would be effective, especially against the background of the increasingly bimodal profiles of commercially available products. (PTX-520 ¶ 225.)

Finally, I find that Teva's argument that a POSA would be motivated to use a single mean peak PK profile to avoid a reemergence of symptoms is not supported by the prior art. Teva's only citation for this assertion is to the testimony of Dr. Young, who stated "Markowitz 2003 also explains that the pharmacokinetic profile of Concerta® provides fewer fluctuations compared to immediate-release formulations. … As previously explained, having 'fewer fluctuations' is important to prevent reemergence of symptoms throughout the day." (DTX-458 ¶ 48.) This statement, however, merely compares Concerta to IR formulations that needed to be taken several times per day, not to the PK profiles of bimodal ER formulations (*See* DTX-460 ¶ 60.) Teva presents no evidence that the reemergence of symptoms during the day was a concern for

[27] Teva cites Dr. Young's statement that Concerta had a "single, ascending peak." (DTX-458 ¶ 14.) This statement, however, is merely a conclusory assertion not supported by any references. The statement from Markowitz 2003 that the PK profile of Metadate CD "is biphasic in nature and distinctly different from that of Concerta" (JTX-091_0012) does not imply that Concerta is not bimodal, simply that Metadate CD is more distinctly bimodal than Concerta, which is undoubtedly true but not relevant.

bimodal ER formulations. I therefore reject the argument that a POSA would have been motivated to pursue a single mean peak formulation in order to avoid reemergence of symptoms.

In sum, I conclude that a POSA would not have been motivated to target a single mean peak PK profile for an ER formulation.[28] The trend in commercially available ER formulations was increasingly bimodal and Teva cites no prior art that would teach a POSA to ignore this trend and instead aim to create and ER formulation with a single mean peak. I thus find that this aspect of claim 22 of the '399 patent and claim 37 of the '544 patent was not obvious.

Combination of parameters. Finally, because I found that it would not have been obvious to a POSA to use a single mean peak PK profile, I find that the combination of PK attributes also cannot be found invalid as obvious.

e. *Objective considerations*

The parties disagree on the objective-considerations aspect of the obviousness inquiry. Tris presents evidence of unexpected results and teaching away, long-felt but unmet need, industry praise, commercial success, and copying, while Teva contends that there is no evidence of any objective indicia of non-obviousness. (Pl. Br. at 44; Def. Br. at 45.) In the course of the discussion above, I have already made findings related to some of the objective indicia, which I revisit here, but overall, I find that the objective indicia are of mixed significance and are insufficient to alter the obviousness findings made thus far.

Teaching away. I have already found that prior art, though perhaps discouraging in some respects, did not actually teach away from developing a chewable ER MPH tablet and did not teach away from using a single mean peak PK profile. I thus find this factor to be neutral as to obviousness.

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[28] I deny as moot Tris's motion in limine no. 3 and decline to strike Dr. Forrest's testimony. (DE 156 at 9–11.) Insofar as Dr. Forrest attempted to establish that targeting a single mean peak was obvious because having a T_{max} within the claimed range was obvious, I disagree, but I have given his views full consideration.

Long Felt, Unmet Need. Tris argues that there was a long felt, unmet need for an ER chewable MPH formulation because there are a significant number of children who could not or would not swallow existing ER pills. (PTX-520 ¶ 167, 175, 181, 186; DTX-458 ¶ 57; PTX-516 ¶ 224–26.) IR chewable formulations had the well-known downsides of all IR formulations (most prominently, repeated dosing), and using the "sprinkle" technique was not reliable. (PTX-520 ¶ 207; DTX-458 ¶ 13, 35, 38, 41, 55–56.) Teva responds that there were ER formulations on the market, and that one cannot show an unmet need if there are alternatives, even if the new product would be preferable in some way. (Def. Br. at 47 (citing *AstraZeneca LP v. Breath Ltd.*, 88 F. Supp. 3d 326, 388 (D.N.J.), *aff'd*, 603 F. App'x 999 (Fed. Cir. 2015).) I find that Teva's argument inappropriately ignores the numerous drawbacks of the preexisting ER formulations and that this factor thus weighs in favor of non-obviousness.

Industry Praise. Tris cites a number of examples of industry praise. (PTX 514 ¶ 84–90.) Teva responds that most of these instances of praise are either authored by Tris or Pfizer employees or are bare citations that do not actually "praise" QuilliChew but merely state that it can be chewed. (Def. Response at 39–40.) Although I agree that a number of the citations can be discounted, at least one meets the criteria of praise that is both actual and independent. Andrew Cutler and Gregory Mattingly's article "Beyond the Pill: New Medication Delivery options for ADHD," published in a peer-reviewed journal, states that "[t]his formulation not only circumvents the need for swallowing intact pills but also appeals to patients who prefer to chew their medications." (JTX-130_0007.) While not the most glowing praise one could imagine, it weighs marginally in favor of non-obviousness.

Copying. Tris has pointed to Teva's ANDA product as an example of copying. In addition, Ascent Pharmaceuticals has sought FDA approval to make a generic version of QuilliChew. (PTX-514 ¶ 94.) Copying in the ANDA context, however, constitutes little more than compliance with the FDA

requirement of bioequivalence. *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013). The desire to market a profitable ANDA product, while not wholly irrelevant, is not strongly probative of this factor. *See id.* I find that the copying factor is largely neutral.[29]

Commercial Success. Finally, the parties disagree about the extent of QuilliChew's commercial success. Tris's sole argument for commercial success is that over a million prescriptions for QuilliChew have been written.[30] (Pl. Br. at 47.) Teva, in contrast, offered the evidence of Mr. Hoffman regarding the small share that QuilliChew has in the relevant market and the large number of discounts that have been given out to improve sales. (Def. Br. at 48.) Commercial success is a close question, and one perhaps confounded by the effect of the COVID pandemic and the narrowness of QuilliChew's market. Tris has put forward no other convincing evidence of commercial success, however, so I find that this factor is neutral to slightly positive.

To summarize the objective factors: I find that the long felt, unmet need and industry praise factors weigh somewhat in favor of non-obviousness, while the remaining factors are in the neutral range. The small boost that these findings give to Tris's case for non-obviousness is not sufficient to disturb my findings, *supra*, that 1) claim 24 of the '545 patent as well as 2) the $AUC_{0-\infty}$ and C_{max} elements of claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent are invalid for obviousness.

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[29] I must reject the use of PTX-514 ¶ 93 as requested in Teva's motion in limine no. 3. In its brief in opposition to the motion in limine, Tris claims that "This statement is ***not*** testimony offering an opinion regarding objective indicia of nonobviousness" (DE 157 at 9), but then cites the same statement in its main brief. (Pl. Br. at 48). Teva's motion in limine no. 3 is otherwise denied.

[30] In its response brief, Tris repeats this argument and attacks Mr. Hoffman's testimony. (Pl. Response at 50.) Tris does not put forward market share evidence in its brief and I thus deny as moot element (c) of Teva's motion in limine no. 3. (DE 153 at 13.)

2. Indefiniteness of Figure 1 Terms (relevant to '399 Patent, claim 24; '545 Patent, claims 23 & 28)

To complete the invalidity discussion, I move on from the issue of obviousness to that of indefiniteness. The claim of indefiniteness focuses on whether the Figure 1 Terms (contained in '399 Patent, claim 24; '545 Patent, claims 23 & 28) provide a POSA sufficient clarity to determine whether a new product's PK profile is "essentially the same" as Figure 1.

a. Legal Standard

The specification of a patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [its] invention." 35 U.S.C. § 112, ¶ 2. The U.S. Supreme Court has held that courts should hold a claim to be indefinite and therefore, invalid, "if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, *i.e.*, what subject matter is covered by the exclusive rights of the patent. *Halliburton Energy Servs., Inc. v. M–I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("[T]he primary purpose of the requirement is 'to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.'") (quoting *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, (1938)). In other words,

> [a] patent holder should know what [it] owns, and the public should know what [it] does not. For this reason, the patent laws require inventors to describe their work in "full, clear, concise, and exact terms," 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the

> promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002).

The indefiniteness inquiry requires that the claim terms be read from the informed perspective of a POSA. *Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006). However, "[e]ven if a claim term's definition can be reduced to words, it is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Halliburton Energy Servs., Inc. v. M–I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008). Claims that are so subjective as to be "insolubly ambiguous," such as a requirement that a screen be "aesthetically pleasing," are indefinite and therefore invalid. *Id.* at 1250 (quoting *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347, 1352 (Fed. Cir. 2005)). Similarly, claims that are "purely subjective," for example a limitation that content be displayed "in an unobtrusive manner" are also indefinite and therefore invalid. *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1378 (Fed. Cir. 2017) (quoting *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014)). Patent law, however, recognizes the inherent limitations of language to describe inventions, and courts have therefore refused to hold that all terms of degree are indefinite. *Sonix Tech.*, 844 F. 3d at 1378; *see also Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005) ("a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement"). In short, the indefiniteness inquiry seeks to determine whether a POSA pursuing a related invention would be able to determine if his or her invention infringed the terms of the asserted patent. Terms of degree are acceptable, within limits, and the patent itself need not set out a mathematical formula to determine if a new invention is too similar, so long as the patent's limitations are not insolubly ambiguous or purely subjective. As with other invalidity arguments, invalidity due to indefiniteness must be proven by clear

and convincing evidence. 35 U.S.C. § 282; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

b. Discussion

Teva puts forward four arguments to demonstrate that the Figure 1 Terms are indefinite because "essentially the same" is a term of degree without objective boundaries, and a POSA therefore could not discern if a new invention infringed the asserted terms. (Def. Br. at 16.) First, Teva argues that the patent itself gives no objective measures to inform a POSA what "essentially the same means." (*Id.* 16–17.) Second, it argues that Dr. Jusko's four-factor method to determine essential sameness is not grounded in the specifications of the patent itself and was created only for the purposes of this litigation.[31] (*Id.* at 17.) Third, Teva argues that even if I accept Dr. Jusko's four-factor method, it fails to give a POSA reasonable certainty because Dr. Jusko provides no method to weigh the relative importance of the four factors. (*Id.* at 18.) Finally, Teva argues that because there are multiple potentially conflicting ways to determine if one PK profile is essentially the same as another, the Figure 1 Terms are indefinite. (*Id.* at 18–19.)

Tris, in contrast, argues that a POSA would be able to discern whether the PK profile of an invention is "essentially the same" as Figure 1 as construed by this court. (Pl. Response at 22–23.) Specifically, it argues that Dr. Jusko did not pull his four-factor test out of the air, but derived it by applying ordinary expertise to the disclosures in the patents. (*Id.* at 23–25.) Finally, Tris argues that although the patents mention different types of variance analyses, they do not bespeak any conflict in the means of analyzing the variance of Figure 1. (*Id.* at 26.)

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[31] Dr. Jusko testified that "a POSA would be able to discern whether the pharmacokinetic profile of an accused product fell within the scope of the term by applying four factors:" 1) claims and specification, (2) visual comparison, (3) number of subjects / experimental design, and (4) product formulations. (PTX-518 ¶ 263.)

I find that the specifications of the patent are clear enough to give a POSA reasonable certainty as to whether an invented drug infringed the patent and therefore find that the Figure 1 Terms are not invalid for indefiniteness.

I begin with a discussion of the first of Dr. Jusko's four factors, because I find it to be the most important. Dr. Jusko testified that to find out if a new drug's PK profile was "essentially the same" as Figure 1, a POSA would "[a]nalyze the comparator formulation against the claims and specification of the Asserted Patents." (PTX-518 ¶ 263.) This factor is clearly grounded in the specifications of the patent. Such grounding matters because Figure 1 is not merely a descriptive sketch of the shape of a curve, but rather is a graphical illustration of the PK profile data for QuilliChew.[32] It reflects the claimed PK parameters, such as AUC, T_{max}, C_{max}, and a single mean peak. As I have discussed at length, ranges for those parameters are disclosed and claimed by the patent. If a comparator formulation does not fall within those parameters, a POSA would know that its PK profile is not essentially the same as Figure 1. For example, a bimodal PK profile would not be essentially the same as Figure 1.[33] I thus find that the fact that the PK parameters that relate to Figure 1 are disclosed in the patent weighs against a finding of indefiniteness.

Second, I agree with Dr. Jusko that a POSA would conduct a visual comparison of a PK profile with Figure 1. Because Figure 1 is a visual graph, the idea that a POSA would conduct a visual comparison is grounded in the specification. Figure 1, by including a graph of the PK Profile of Methylin, gives an illustrative example of a PK curve that is not "essentially the same" as the claimed PK profile included in Figure 1. It should be obvious to any observer that the Methylin PK profile (as well as, for example, the PK profile of Focalin

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[32] Dr. Jusko testified that it was generated from example 5. (PTX-517 ¶ 25–28.) Tris confirms that it is derived from the information in example 5 of the patent. (Pl. Response at 25; JTX-1 at 29:1–20.) This is true insofar as the cited text describes a PK dissolution study.

[33] That is not to say that there can be no parameter overlap. It is easy to envision a non-infringing PK profile that shares, *e.g.,* a T_{max} with Figure 1 but is otherwise entirely different.

XR) is not essentially the same as Figure 1. Such a visual inspection implicitly captures elements of Dr. Jusko's first factor. If a PK profile has a radically different AUC from that of Figure 1 or is bimodal, such differences would be readily discernible upon comparing the appearance of the two profiles.

Dr. Jusko's third factor is essentially a restatement of basic statistics. When generating a mean PK curve based on experimental dissolution data, the variance of the data will be reduced to the extent that more subjects are included in the mean. Generally, a PK profile generated from a dissolution study with 10 participants may *look* different from (or the same as) Figure 1; a POSA may be far more confident, however, that a PK profile generated from a dissolution study with 1000 participants is *actually* different from (or the same as) Figure 1. This factor is not grounded in the patent specifications as such, but a POSA is assumed to understand variance or confidence intervals from experimental data. In short, a POSA would know that, in general, more data points tend to imply more accuracy and less statistical variance.

Dr. Jusko's fourth factor again reflects the basic scientific knowledge of a POSA. It is based in the specifications insofar as Example 2 of the patent describes the formulation of the product. (Pl. Response at 25; JTX-1 at 23:15–24:67.) Generally, a POSA would know that the more similar a new formulation is to the claimed formulation, the more likely it is that the PK profile of the new formulation would match Figure 1. For example, if two drugs are chemically identical, they should affect a patient in the same way (this is the theory that underlies the FDA's ANDA bioequivalence process). By the same token, a POSA would know that by creating an identical formulation, he or she had likely infringed other patent limitations as well, such as the barrier coating claims or the ratio of IR to ER components.

Overall, I am persuaded that Dr. Jusko's four factor analysis represents the type of analysis that a POSA would perform to determine if a new formulation infringed the Figure 1 Terms. The first two factors are the most important. By reading the patent, a POSA would know with a reasonable certainty that if the PK parameters of the new formulation matched the claimed

PK parameters, the new formulation would likely infringe the Figure 1 Terms as well. Similarly, a POSA could graph the mean PK profile generated by the POSA's own dissolution study and compare it visually to Figure 1, and could tell if the two graphs were essentially the same.[34] I do not find it particularly meaningful that Dr. Jusko did not give pre-assigned weights to the four factors vis-a-vis each other. (1T at 177:4–8.) The four factors are interrelated, and a POSA would use these different factors to make a holistic judgment about whether the PK profile of a new formulation was essentially the same as Figure 1. The law does not require that a POSA have absolute certainty that a new invention does not infringe the asserted patent, only "reasonable certainty." *Nautilus v. Biosig*, 572 U.S. at 901.

I address Teva's contention that the Figure 1 Terms are indefinite because there are multiple methods by which a POSA could determine if the PK profiles are essentially the same. (Def. Br. at 18–19.) As noted above, I was persuaded by testimony that a POSA could and would determine if the PK profiles were essentially the same as Figure 1 by using a holistic evaluation along the lines laid out by Dr. Jusko. Teva points to what it terms a contradiction or inconsistency: another section of the patent, Teva points out, references ANOVA and 90% confidence intervals, and defines "about" to mean plus or minus 10%. None of those methods, however, are stated in relation to the Figure 1 Terms. (*Id.*; JTX-001 at 8:12–17, 20:30–49.)

Finally, I find that Teva's citation to *Teva Pharms. USA, Inc. v. Sandoz, Inc.* is not on point. 789 F.3d 1335 (Fed. Cir. 2015). There, the Federal Circuit held that although the patent contained limitations related to "molecular weight," it did not specify which of the three scientifically valid measures should be used to determine the molecular weight of a new formulation. *Id.* at 1344–45. Thus, a POSA would not be able to determine with reasonable

[34] This is where factors three and four come in. If the PK profile was only slightly different, but was based on a robust study with little variance or a very different formulation, the POSA would have more confidence that the new formulation did not infringe the Figure 1 Terms.

certainty if a new product infringed, because all three measures were scientifically valid, and no amount of expertise would reveal which was intended. *Id.* That molecular weight issue is distinct from the "essentially the same" determination here. In *Sandoz,* there were three established methods, but no way to determine which was intended to apply. Here, as I have found, a POSA could use a holistic comparison to determine with reasonable certainty that a new formulation did not infringe the Figure 1 Terms.

I thus find that the Figure 1 Terms are not invalid for indefiniteness.

My invalidity findings are summarized in the following table:

Fully Invalid for obviousness	Claim 24 of the '545 patent.
Valid when shorn of limitations related to $AUC_{0-\infty}$ and C_{max} that are included in the related independent claims	Claims 22 and 24 of the '399 patent; Claim 37 of the '544 patent; Claims 17, 23, and 28 of the '545 patent; Claim 28 of the '494 patent.
Fully Valid	Claim 23 of the '495 patent.

B. Infringement

In this section, I assume *arguendo* that the asserted patents are fully valid and consider in the alternative whether they have been infringed. I find that Tris has demonstrated by a preponderance of the evidence that the asserted claims, assuming they are valid, have been infringed by Teva's ANDA product.[35] Because I have found that claim 24 of the '545 patent is invalid, I find that that claim is not infringed.

1. Therapeutically effective extended release profile (relevant to '399 patent claims 22 and 24; '544 patent claim 37; '545 patent claims 17, 23, 24, and 28)

[35] Again, Teva has stipulated to infringement of the asserted claim 28 of the '494 patent and claim 23 of the '495 patent.

I begin by examining whether Teva's ANDA product infringes the asserted claims 22 and 24 of the '399 patent; claim 37 of the '544 patent; and claims 17, 23, 24, and 28 of the '545 patent. Those claims disclose an MPH tablet with a "therapeutically effective extended release profile," which I have construed as meaning "an extended release profile *associated with* a therapeutic effect that lasts for a period of at least about 12 hours." (*Id.* at 15 (emphasis added).) In this context "about" incorporates a margin of 10%, and hence reduces the minimum claimed period of time to 10.8 hours. Teva disputes that its ANDA product is associated with a therapeutic effect that lasts 10.8 hours. (Def. Br. at 4.) The somewhat counterintuitive feature of Teva's argument is that Teva claims that *neither* QuilliChew nor its own product satisfies the 10.8 hour minimum.

There have been no studies of the therapeutic effect of Teva's ANDA product. Rather, because Teva's generic ANDA product is bioequivalent to QuilliChew, the parties appear to agree that it must have the same duration of effect as QuilliChew. (*Id.* at 4–5.) The question therefore comes down to whether QuilliChew's duration of effect (and therefore the Teva generic's duration of effect) is greater than 10.8 hours and thus falls within the range claimed by the asserted patents. (*See* Pl. Br. at 19.) If I find that Tris has shown by a preponderance of the evidence that QuilliChew, and thus Teva's ANDA product, has a therapeutic effect of more than 10.8 hours, I must find that Teva's ANDA product infringes this aspect of the asserted claims. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

I begin with both products' labels. (JTX-195 (QuilliChew); JTX-011 (Teva's ANDA product).) Both products' labels state that the products "showed improvement over placebo at 0.75, 2, 4, and 8 hours postdosing." (JTX-011_0013; JTX-195_0009.) These statements are based on a 95% confidence interval, which is equivalent to a p-value of 0.05. (*Id.*) In both cases, the source for this statement is the NextWave study of QuilliChew. (DTX-459 ¶ 101.) The FDA generally permits efficacy claims that are supported with clinical data at a

95% confidence level (p-value of less than 0.05). (PTX-519 ¶ 85.) That same 95% confidence level is generally accepted, as a statistical matter, by clinicians evaluating data. (DTX-459 ¶ 100.) It follows that, applying that FDA standard, Tris (and thus Teva) would not be permitted to claim on the drug's label that the drug was more effective than a placebo at the 10- or 12-hour marks. Physicians, however, are allowed to, and frequently do, prescribe drugs for "off-label" use. (2T 275:12–16, 312:24–313:10.) In addition, the question of infringement, though not unrelated to the FDA's standards for labeling, is distinct. The question is one of fact: whether QuilliChew (and therefore Teva's ANDA product) actually has a therapeutic effect that lasts for longer than 10.8 hours. That question cannot be answered in the negative simply because the label only states that it is effective for 8 hours.

I turn to the NextWave study, which is the only piece of evidence that relates directly to the therapeutic effectiveness of QuilliChew and thus of Teva's ANDA product. The relevant results of the NextWave study are summarized at Section I.E, *supra*. The two values relevant to this infringement discussion are the SKAMP-combined scores at the 10- and 12-hour mark. At both points, the subjects who had been given QuilliChew performed better on average than those given the placebo. At 10 hours, the p-value related to the score difference was 0.133 and at 12 hours the p-value was .206.[36] (JTX-034_0130; 2T at 282:4–283:18; PTX-519 ¶ 118.) The question then is whether this data reveals that QuilliChew (and thus Teva's ANDA product) is "associated with a therapeutic effect" that lasts at least 10.8 hours. I find that it does.

Different levels of proof are appropriate for different contexts, and the context of a patent infringement trial is different from that of the FDA approval process. Although the FDA undoubtedly has good reason for requiring a high threshold for efficacy claims on drug labels, I recognize that the 0.05 p-value

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[36] No measurement was taken at precisely 10.8 hours, but it is reasonable to assume that the p-value of such a measurement would necessarily have been somewhere between 0.133 and 0.206.

cutoff is essentially an arbitrary statistical convention (there is no substantial reason to set the cutoff at 0.05 rather than 0.06 or 0.04).[37] Moreover, I read that statistical convention against the background of patent infringement law, which requires proof by a preponderance of the evidence. In the infringement context, that means the patent holder must prove that infringement is more likely than not to occur (in probabilistic terms, a likelihood greater than 50%).[38] *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1287 (Fed. Cir. 2010).

Here, the NextWave study demonstrates that those subjects who were given QuilliChew had better SKAMP scores, on average, at the 12-hour mark, well past the 10.8-hour threshold. Statistical analysis performed by the researchers generated a 12-hour p-value of 0.206. That p-value equates to a 20.6% chance that the difference between the QuilliChew and control group's scores were the result of random variation and thus a reciprocal 79.4% chance that the differences were the result of QuilliChew's therapeutic effect. I find that this satisfies Tris's light burden to demonstrate by a preponderance of the evidence that Teva's ANDA product is associated with a therapeutic effect that lasts at least 10.8 hours.

I find that this conclusion is bolstered by the specific language of the patents, as I have construed it, and by the SKAMP-change scores. First, the claim language itself: As I construed it in the *Markman* hearing, the claim requires that the drug be "associated with a therapeutic effect" that lasts longer than 10.8 hours. It is easy to imagine language that requires a stricter level of causation, such as "the drug must cause a statistically significant reduction in

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[37] As always, bright line rules have both benefits and downsides. A robust literature has shown that researchers often "p hack," working backward to find results that have a p-value of just less than 0.05. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4359000/

[38] A certain awkwardness is inherent in the notion of proving a 95% probability by a preponderance. I take no position on Dr. McGough's so-called "litigation p-value" which asserts that any p-value lower than 0.49 is sufficient to establish a preponderance of the evidence. (PTX-519 ¶ 92–96.)

ADHD symptoms" or "the drug must eliminate the majority of ADHD symptoms." I find that "is associated with" is broader than, *e.g.*, "causes," and that "therapeutic effect" is broader than, *e.g.*, "therapeutic effect proven to a 95% probability." In short, I find that this particular phrase from the patent language is broad and does not require proof to a 0.05 p-value.

Moreover, there is a second, alternative mode of analysis that leads to the same result, based the Wigal reference's persuasive analysis of the NextWave data using the SKAMP-Change scores. My finding that QuilliChew (and thus Teva's ANDA product) is associated with a therapeutic effect for at least 10.8 hours is also justified by the SKAMP-Change scores. (PTX-519 ¶ 88–92.) As explained in Section I.E, *supra*, the change scores, which adjust for the rebound effect, are highly significant even when assessed at the stricter Bonferroni level. It is true that the decision to look at the data through the lens of SKAMP-Change scores was made *post hoc* (and in fact was brought to prominence by Wigal, not the original researchers). The underlying change-score data, however, were generated by and contained in the original NextWave study, and they bolster the conclusion that QuilliChew has a clinical effect. (Def. Br. at 9.) Again, nothing in the patent specifications requires that therapeutic effect be measured by raw SKAMP scores, and I find that the SKAMP-Change score method, though not necessary to reach a conclusion regarding therapeutic effect, supports that conclusion.

Causation is proverbially difficult to determine, and is a multivalent, context-dependent concept. Causal inference has long been a central arena of scientific and statistical, not to say philosophical, debate. Here, however, the law sets a relatively low burden of proof. To prove infringement Tris need only prove by a preponderance of the evidence that QuilliChew is associated with a therapeutic effect for at least 10.8 hours. Teva has put forward no independent countervailing evidence, and I thus find that Tris has met its burden of proof by showing that there is at least a 79% probability that QuilliChew's therapeutic effect, and not mere chance, accounts for the difference between the two groups at the 12-hour mark of the NextWave study. I thus find that

Teva's ANDA product directly infringes claims 22 and 24 of the '399 patent; claim 37 of the '544 patent; and claims 17, 23, 24, and 28 of the '545 patent.

2. Barrier Coating Weight Percentage (relevant to '399 patent claims 22 & 24 and '544 patent claim 37)

Next, Tris argues that Teva's ANDA product infringes the limitations of the asserted claims related to the weight percentage of the barrier coating of the chewable tablet. Specifically, Tris cites claim 22 and 24 of the '399 patent and claim 37 of the '544 patent.[39] The asserted patents claim a barrier coating weight percentage of 18% w/w to 55% w/w.[40] (PTX-515 ¶ 50–53.) Teva's ANDA product has a barrier coating weight percentage of 17% w/w. (*Id.* ¶ 54; DTX-463 ¶ 231.) Seventeen percent is just outside the range claimed by the asserted patents. Tris therefore resorts to the doctrine of equivalents to argue that Teva's ANDA product infringes. (Pl. Br. at 12.) Teva replies that the doctrine of equivalents does not apply (Def. Br. at 13–14; Def. Response at 8–10) and that the disclosure-dedication doctrine precludes Tris from extending the claimed range (Def Br. at 11–13).

I begin with the doctrine of equivalents. "The doctrine of equivalents requires that the accused product contain each limitation of the claim or its equivalent." *Cortland Line Co. v. Orvis Co.*, 203 F.3d 1351, 1359 (Fed. Cir. 2000). An element in the accused product is equivalent to a claim element if the differences between the two are "insubstantial" to one of ordinary skill in the art. See *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). The primary test for equivalency is the "triple identity" test: "the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as

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[39] Claims 22 and 24 of the '399 patent are dependent on claim 1, while claim 37 of the '544 patent is dependent on claim 28.

[40] The claims read "about 20% w/w to about 50% w/w." Consistent with the parties' agreed meaning of "about," that range is expanded on either end by 10%, to produce a range of 18% to 55%. (PTX-515 ¶ 50-53.)

disclosed in the claim." *Abbott Lab'ys v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009).

At first blush, Teva's creation of a barrier coating with a weight one percentage point outside of the claimed range would seem to implicate the doctrine of equivalents because it uses the same type of coating to perform the same function in the same way, just employing a tiny bit less of it. In fact, Tris claims that when engineering its ANDA product, Teva purposefully reduced the barrier coating percentage of Actavis's similar product from 19% to 17% to fall outside the literal range of the asserted claims. (Pl. Br. at 12.)

Teva, however, argues that the doctrine of equivalents does not apply because the word "about" already captures the full range of equivalents.[41] In support it cites a single case, *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1372 (Fed. Cir. 2008). In Teva's view, *Cohesive* holds that the word "about" limits the use of the doctrine of equivalents. *Cohesive*, however, can readily be distinguished. Here, the asserted patents themselves define "about" as plus or minus 10%. (*See* JTX-001 at 8:12–13.) In *Cohesive*, in contrast, the term "about" was not defined, and the Federal Circuit held that "'about 30 µm' encompasses particle diameters that *perform the same function, in the same way, with the same result* as the 30 µm particles, as long as those diameters are *within the range left open by the specific disclosures of the specification*." *Cohesive*, 543 F.3d at 1372 (emphasis added). The court thus concluded that "by electing to include the broadening word 'about' in the claim, the patentee has in this case already captured what would otherwise be equivalents within the literal scope of the claim." *Id.* In short, the Federal Circuit construed "about," in the absence of a more specific definition, as capturing all equivalents. That is not the case here; in this patent, "about" specifically means

[41] Teva relegates this argument to a footnote its responsive brief. (Def. Response at 10 n.3.) Teva also argues that the doctrine of equivalents does not apply because of the disclosure-dedication doctrine. I discuss that contention at pp. 57–60, *infra*.

+/- 10%, and that definition might or might not extend to the limit of the doctrine of equivalents.

Moreover, subsequent cases have declared that *Cohesive* did not announce a bright line rule, but was instead limited to its facts. *See Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, No. CV171612MNCJB, 2022 WL 2753636, at *2 (D. Del. June 30, 2022). Consequently courts, including the Supreme Court, have applied the doctrine of equivalents to broaden numerical ranges, including those that use "about" and "approximately." *Bayer Healthcare Pharms., Inc. v. River's Edge Pharms., LLC*, No. 1:11-CV-1634-HLM, 2015 WL 11156903, at *6 (N.D. Ga. June 22, 2015) ("It is not logical to conclude that the [patentee] determined … that +/-10% represented the precise range of component that would act in substantially the same way to get substantially the same result. It is more logical, and more consistent with the actual use of the term in this instance, that 'about' is used as a shorthand way to broaden the numbers presented."); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) (allowing the application of the doctrine of equivalents to a range that includes "approximately"). Finally, I find that even if the patent did not include "about" and thus only claimed a range between 20% and 50%, a barrier coating of 17% w/w could still potentially infringe under the doctrine of equivalents. I thus conclude that the inclusion of "about" in the range of the asserted claims does not preclude infringement under the doctrine of equivalents.

I next address the disclosure-dedication doctrine.

The disclosure-dedication doctrine allows a patentee to disclaim an equivalent to a claimed invention by disclosing it, without claiming it, in the patent. Such disclosed alternatives are considered to be dedicated to the public. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) ("when a patent drafter discloses but declines to claim subject matter … this action dedicates that unclaimed subject matter to the public"). The doctrine is not without restriction, however. The rule "does

not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public." Rather, "the disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1363 (Fed. Cir. 2012) (quoting *PSC Computer Products v. Foxconn International, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)). In addition, "before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee *as an alternative to a claim limitation*." *Id.* (quoting *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005)) (emphasis added).

The classic example of the disclosure-dedication doctrine comes from *Johnson & Johnson*, in which the patent at issue disclosed "[w]hile aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used." 285 F.3d at 1050. The Federal Circuit, sitting en banc, held that by claiming aluminum but disclosing that other metals could be used as an alternative, the patentee could not invoke the doctrine of equivalents to cover steel as a mutually exclusive alternative to aluminum. *Id.* at 1055. In short, the asserted patent in *Johnson & Johnson* claimed aluminum but disclosed that, in the alternative, the substrate could be made with steel. Aluminum and steel are mutually exclusive in the sense that the substrate must be made from one or the other, so the Federal Circuit held that the mutually exclusive alternative of steel, because it was disclosed but not claimed, was dedicated to the public. An accused device employing a steel substrate would therefore not infringe under the doctrine of equivalents.

Here, Teva argues that the disclosure-dedication doctrine should apply because the specifications of the asserted patents "disclose alternative weight percentages of barrier coating amounts." (Def. Br. at 11.) For example, the specification of the '399 patent states, in relevant part, "In one embodiment, the barrier coating layer is about 10% to about 70%, by weight, or about 15%

to about 65%, by weight." (JTX-001 at 12:4–6.) This disclosed range is clearly wider than the claimed range of about 20% to about 50%, and the 17% by-weight barrier coating of Teva's ANDA product falls within that broader disclosed range of 10–70% or 15–65%. The key question is whether that disclosed broader range is a mutually exclusive alternative to the claimed range within the meaning of the disclosure-dedication doctrine.

Tris argues that the disclosure-dedication doctrine does not apply. The broader disclosed range, according to Tris, cannot be an alternative to the claimed range because the disclosed range fully subsumes the claimed range. Thus, Tris argues, the two ranges are not mutually exclusive, because a single product could comply with both. (Pl. Response at 13–14.) I agree that the broader range is not a mutually exclusive alternative and thus find that the disclosure-dedication doctrine does not apply.

For the proposition that numerical ranges can be alternatives, Teva cites a single unpublished case from 1998. (Def. Br. at 12 (citing *Brunswick Corp. v. United States*, 1998 WL 163700 (Fed. Cir. Mar. 31, 1998).) In that case, the asserted patent claimed a range of resistivity between 100 and 1000 ohms but also disclosed "resistivities below the claimed range of 100 to 1000 ohms." *Brunswick*, 1998 WL 163700, at *5. The allegedly infringing resistivities at issue were between 74 and 87 ohms. The Federal Circuit held that resistivities below 100 ohms had been disclosed by the patent, but did not overlap with the claimed range. The two were mutually exclusive, in that a single product cannot have a resistivity that is both below 100 ohms and between 100 and 1000 ohms.

Brunswick is therefore not on point. Although this case also involves a numerical range, the similarities end there. The key difference is that here, the claimed range is a subset of the disclosed range, whereas in *Brunswick* the disclosed range was entirely separate from the claimed range. I find that as a matter of logic, a subset of a larger range cannot be mutually exclusive with the larger range, because, by definition, they overlap. In short, a broader and an

included narrower range are not alternatives in the way that aluminum and steel are alternatives.[42] Therefore I find that the doctrine of equivalents is not ruled out in relation to the barrier coating of Teva's ANDA product.

Finally, I apply the doctrine of equivalents and find that Teva's ANDA product does infringe claims 22 and 24 of the '399 patent and claim 37 of the '544 patent. Teva puts forward no factual argument that it does not, and I find that the barrier coating of Teva's ANDA product "performs substantially the same function, in substantially the same way, to achieve substantially the same result" as the barrier coating claimed in the asserted patents. *Abbott Lab'ys v. Sandoz,* 566 F.3d at 1296.

3. PK Limitations (relevant to '545 patent claim 17)

Tris argues that Teva's ANDA product infringes the asserted claims related to the PK profile. Specifically, it cites claim 17 of the '545 patent, which states that "the tablet has a pharmacokinetic profile for racemic methylphenidate comprising a single mean plasma concentration peak which is about 4 hours to about 5.25 hours under fasted conditions." (JTX-003 at 33.) The inclusion of "about" widens the upper and lower boundaries of the range by 10%, to be "3.6 hours to 4.4 hours to 4.72 hours to 5.78 hours." (DTX-460 ¶ 84.) I have construed a single mean peak as "a mean plasma concentration profile with a single peak, but one that need not be a single point." (DE 106 at 22–23.) I have also, in the context of the Figure 1 Terms, construed "has" as not requiring an absolute, point by point, identity. (*Id.* at 33.) I find the same is true here. Thus, a single mean peak is distinct from the time of maximum concentration (T_{max}), which is a single point.

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[42] Teva suggests that I should separate the disclosed range into discrete parts and find that the patent discloses the range of 9% to 17% w/w rather than the range of 9% to 77% w/w actually disclosed in the patent. (Def. Br. at 12–13.) If I were to do so, the case would be more similar to *Brunswick*, because the disclosed range (as divided) would not overlap with the claimed range. I find, however, that it would be inappropriate to substitute my own definition of the disclosed range to the range that of 9% to 77% w/w that is actually disclosed in the patent.

Teva argues that its ANDA product does not infringe this claim because the ANDA product "reaches its maximum concentration before this claimed range." (Def. Br. at 14.) That, however, is the wrong inquiry. The question is not where the T_{max} is located but where the peak is located, and the peak need not be a single point. In addition, Teva argues that the claim language requires "that the beginning and end of the peak should correspond with the approximate beginning and end of the claimed range."[43] (*Id.* at 15.) I reject this definition and instead find that under the claim language, as I have construed it, it is sufficient that, as here, a majority of the peak duration falls within the claimed range, *i.e.*, between 3.6 and 5.78 hours.

I find that the single mean peak in Teva's ANDA product, according to Teva's dissolution study, is between 2.25 hours and 5 hours. (JTX-027 at 61; PTX-517 ¶ 94.[44]) Thus, 1.4 hours, representing 51% of the length of the Teva ANDA product's 2.75-hour peak, occurs within the claimed range. Because a (bare) majority of the ANDA Product's peak occurs within the claimed range, I find that it infringes claim 17 of the '545 patent.

4. Figure 1 Terms

Finally, Tris argues that Teva's ANDA product infringes the Figure 1 Terms because its PK profile is essentially the same as that portrayed in Figure 1.

Tris first argues that because the label of Teva's ANDA product includes Figure 1, that proves infringement. (Pl. Br. at 17.) The PK profile graph in the ANDA label (JTX-011 at 10) is identical to the PK profile graph in QuilliChew's

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[43] Teva also argues that the claim language requires "at a minimum that the curve reaches its maximum concentration within the claimed time range." (Def. Br. at 15.) The claim language contains no such requirement.

[44] Teva objects to Dr. Jusko's testimony that Teva's ANDA product has a single mean peak as undisclosed expert testimony. (DTX-467 at 2.) This issue is also invoked in Teva's Motion in limine no. 1. (DE 154 at 1–3.) I overrule this objection and deny motion in limine no. 1 because Dr. Jusko based his analysis on data that was revealed in his opening report. In addition, having independently reviewed the dissolution data of Teva's ANDA product, I agree that it has a single mean peak. (JTX-027.)

label and hence to the fasted curve of Figure 1 (JTX-195 at 8; JTX-001_0009). The only difference between the two figures is that the ANDA product's label states that the graph depicts, not QuilliChew, but "Methylphenidate Hydrochloride Extended-Release Chewable Tablets." (JTX-011 at 10.) Teva, which did perform its own dissolution studies, provides no coherent account of why it included Figure 1 rather than its own data on its ANDA label.[45] Teva does argue that "the inclusion of the QuilliChew fasted curve in Teva's label is not an affirmative representation to the FDA or anyone else about the PK profile of Teva's product." (Def. Br. at 20–21.) But the purpose of the label is to inform patients and physicians about what the drug does. The label includes no disclaimer or other language stating that the PK profile graph depicts the PK profile of QuilliChew or that it differs from that of the ANDA product. Anyone reading the label, whether expert or not, would conclude that Teva's ANDA product has the same PK profile as Figure 1 in its label.

That, however, is not the end of the matter because the three Figure 1 Terms include slightly different language. Claim 23 of the '545 patent requires only that the accused product be essentially the same "*fasting* plasma concentration curve of FIG. 1 from about 0 to about 8 hours." (JTX-003 at 33.) Claim 28 of the '545 patent is broadly similar but covers a PK profile of an accused product that "comprises one or more of an AUC_{0-3} of the *fasting or fed* plasma concentration curve of FIG. 1 or an AUC_{0-4} of the *fasting or fed* plasma concentration curve of FIG. 1." (JTX-003 at 34.) Finally, claim 24 of the '399 patent covers a PK profile "as determined under *fasted and fed* conditions … is equivalent to the plasma concentration curve of FIG. 1 from about 0 to about 8 hours." (JTX-001 at 33.)

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[45] Teva argues that Tris has the burden of proving that the FDA would have allowed Teva to deviate from QuilliChew's label. (Def. Response at 15–16.) I disagree. Rather, I find that Tris argues that the label proves infringement, and Teva's defense to that assertion is an argument, for which it provides no evidence, that the FDA required it to include the PK profile of a different drug, QuilliChew, on its label. While Tris bears the burden of proof on infringement, Teva bears it with regard to its affirmative defenses.

Claims 23 and 28 of the '545 patent require only that the PK profile be essentially the same as the fasted curve of Figure 1. I thus find that by including the fasted curve of Figure 1 in its ANDA label, Teva has infringed claims 23 and 28.

Claim 24 of the '399 patent is more complicated, however. That claim requires that the allegedly infringing PK profile be the equivalent of Figure 1 under both fasted and fed conditions. It is true that the graph in Teva's ANDA label shows only the fasting PK curve. The very next line, however, describes the "food effect" using a description identical to QuilliChew's label (except for the name of the drug): "High-fat meal had no effect on the time to peak concentration, and increased C_{max} and systemic exposure (AUC_{inf}) of methylphenidate by about 20% and 4%, respectively, after a single dose administration of 40 mg methylphenidate hydrochloride extended-release chewable tablets." (JTX-011 at 11; *compare* JTX-195 at 8.) This passage, which describes the fed curve in a manner identical the fed curve of QuilliChew, is sufficient to meet the limitation of claim 24 of the '399 patent that requires the profile to be determined under both fasted and fed conditions. The "food effect" description describes, albeit in words rather than graphically, the fed PK profile so as to infringe claim 24 of the '399 patent.

I therefore find that Teva's ANDA product infringes all three of the Figure 1 Terms.

Although I find that Teva's ANDA product label is sufficient to establish infringement, in the alternative I briefly compare Figure 1 to the PK profile of Teva's ANDA product as established in Teva's own dissolution study. Teva argues that the PK profile of its ANDA product is not "essentially the same" as Figure 1. (Def. Br. at 19–21; Def. Response at 16.) Here, Teva relies largely on statistical calculations conducted by Dr. Forrest. (DTX-461 ¶ 147–57.) I have already found, however, that Dr. Jusko's holistic four-factor approach provides more appropriate mode of comparison that a POSA would use. *See* Section II.A.2.b, *supra*. Applying Dr. Jusko's approach yields the same result, *i.e.,* that Teva's ANDA product is essentially the same as Figure 1. That is so because

Teva's ANDA product shares PK parameters including a single mean peak with the asserted claims, is formulated in largely the same way, and a visual comparison between the two graphs reveals a great deal of similarity. (PTX-517 ¶ 122–32.) I thus conclude that even if I decided to ignore the label of Teva's ANDA product, I would still find that the PK profile taken from Teva's own dissolution study of its ANDA product is essentially the same as Figure 1 and thus infringes the Figure 1 Terms.

To summarize my infringement conclusions: I find that Teva's ANDA product infringes all valid asserted claims. Because I have found invalid claim 24 of the '545 patent, that claim is not infringed by Teva's ANDA product. In addition, because I have found invalid the $AUC_{0-\infty}$ and C_{max} elements of the claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent, Teva's ANDA product cannot be said to infringe those claims based solely on those $AUC_{0-\infty}$ and C_{max} limitations. But I find nevertheless that the remaining, valid elements of claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, and 28 of the '545 patent, and claim 28 of the '494 patent are infringed by Teva's ANDA product.

My infringement findings are summarized in the following table. (Claims marked with an asterisk* are those in which the invalid $AUC_{0-\infty}$ and C_{max} limitations incorporated from the associated independent claim are deemed struck.)

'399 patent, claim 22*	Infringed
'399 patent, claim 24*	Infringed
'544 patent, claim 37*	Infringed
'545 patent, claim 17*	Infringed
'545 patent, claim 23*	Infringed
'545 patent, claim 24	Not infringed (claim invalid)
'545 patent, claim 28*	Infringed

'494 patent, claim 28*	Infringed
'495 patent, claim 23	Infringed

III. CONCLUSION

I find that Teva has established by clear and convincing evidence that that the following claims are **invalid** for obviousness: 1) Claim 24 of the '545 patent and 2) the $AUC_{0-\infty}$ and C_{max} elements of the claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, 24, and 28 of the '545 patent, and claim 28 of the '494 patent. Claim 23 of the '495 patent is **fully valid**. When shorn of the invalid limitations related to $AUC_{0-\infty}$ and C_{max}, claims 22 and 24 of the '399 patent, claim 37 of the '544 patent, claims 17, 23, and 28 of the '545 patent, and claim 28 of the '494 patent are **valid**. Tris has shown by a preponderance of the evidence that all valid asserted claims (*i.e.*, all asserted claims except for claim 24 of the '545 patent) **were infringed** by Teva's ANDA product.

Dated: August 16, 2022

/s/ Kevin McNulty

KEVIN MCNULTY
United States District Judge